SUPPORTING STATEMENT: PART A

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Traumatic Brain Injury Disparities in Rural Areas (TBIDRA)

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Table of Contents

LIST OF ATTACHMENTS

Attachment 1. Public Health Service Act (42 U.S.C. 241)

Attachment 2. 60-Day Federal Register Notice (FRN)

Attachment 3. Public Comments and responses

Attachment 4. Focus group invitation email

Attachment 5. Focus group screener

Attachment 6. Focus group consent form

Attachment 7. Focus group questionnaire

Attachment 8. Focus group discussion guide

Attachment 19. Privacy Impact Assessment (PIA)

Attachment 10. IRB exemption

Summary Table

- **Goals of the Study**:
  (1) To conduct formative research to understand challenges that rural healthcare providers face when diagnosing, treating, and managing traumatic brain injury (TBI) so that we are able to modify our materials (trainings, dissemination materials, messages, recommendations) for the rural setting. Toward this end, some of the specific information we intend to capture includes:
  Understanding how rural clinicians diagnose and manage patients who sustain a TBI; gathering general information about what rural providers see as the main challenges they face in diagnosing and managing patients who have sustained a TBI; identifying potential innovative approaches that rural providers have used to overcome these challenges; identifying whether, and how, state policies on Return to Learn and Return to Play influence rural TBI care

  (2) Identify areas for future research that will allow us to better understand these challenges and potential ways to address them.

- **Intended use of the resulting data:** The results of this information collection will inform CDC's immediate and future outreach and education for rural healthcare providers, including CDC's "HEADS UP for Healthcare Providers" educational program, and the recently-released pediatric mild TBI guideline.

- **Methods to be used to collect data:** Up to six in-person or virtual focus groups of 8-10 physicians, NPs, and/or PAs, for a total of up to 60 respondents. These focus groups will include rural physicians, nurse practitioners, and physician assistants working in primary care (e.g., family medicine, internal medicine, pediatrics) settings or emergency departments.

- **How data will be analyzed:** The qualitative focus group data will be analyzed using a themes-based approach, guided by the research questions, specifically focusing on the facilitators and barriers identified by rural healthcare providers in diagnosing, treating, referring, and managing TBI.

SECTION A - JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

CDC requests OMB approval for two years for this NEW data collection. The study, "Traumatic Brain Injury Disparities in Rural Areas (TBIDRA)" will help CDC to better understand the challenges that rural healthcare providers face in diagnosing, treating, and managing mild TBIs - the most common type of TBI - and identify areas for future research that will allow us to better understand these challenges and potential ways to address them.

Research into rural/urban differences in traumatic brain injury (TBI) in the U.S. is scarce, particularly at the national level. However, the evidence that does exist suggests that residents of rural areas have both higher incidence and higher mortality rates from TBI than do residents of urban areas,[1,2,3,4] and that the prevalence of TBI-related disability in rural geographical areas is higher than in urban and suburban areas.[5] Mild TBIs make up the preponderance of TBI cases – one systematic review estimated that 70-90% of all TBIs are mild[6] - and some studies have found that there are urban/rural differences related to patient age, severity of injury and the most frequent mechanisms of injury.[7]

The obstacles healthcare providers and patients face in rural areas are vastly different from those in urban areas. Workforce shortage problems (access to physicians), lack of advanced TBI training, and transportation issues are among the barriers rural patients encounter in their quest for high-quality, comprehensive TBI care.[3]

Although this identified gap in TBI services exists in rural areas of the United States, there is little published research specifically related to the challenges rural providers face in TBI diagnosis and treatment,[8,9] and even less examination of effective ways to address gaps in service aimed at improving TBI outcomes. The National Center for Injury Prevention and Control at the CDC (CDC's Injury Center), in a 2015 "Report to Congress on TBI in the United States," stated that certain population groups, including residents of rural geographic areas, require special

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[1] Chapital A.D. (2005). Traumatic brain injury: outcomes of a rural versus urban population over a 5 year period. University of Hawaii, Manoa, Hawaii.

[2] Bazarian JJ, McClung J, Shah MN, Chen YT, Flesher W, Kraus J. (2003). Mild traumatic brain injury in the United States, 1998-2000. *Brain Injury, 19(2)*: 85-91.

[3] Johnstone, B., Nossaman, L. D., Schopp, L. H., Holmquist, L., & Rupright, S. J. (2002). Distribution of services and supports for people with traumatic brain injury in rural and urban Missouri. *The Journal of Rural Health, 18*(1), 109-117.

[4] Leonhard MJ, Wright DA, Fu R, Lehrfeld DP, Carlson KF. (2015). Urban/rural disparities in Oregon pediatric traumatic brain injury. *Injury Epidemiology 2:* 32.

[5] Kaye SH (1997). *Disability Watch: The Status of People with Disabilities in the US.* Volcano Press., Inc., Volcano, CA. Sponsored by National Institute on Disability and Rehabilitation Research, Washington, DC.

[6] Carroll L.J. et al. Prognosis for mild traumatic brain injury: Results of the WHO Collaborating Centre Task Force on Mild Traumatic Brain Injury. J Rehabil Med. 2004;43 (Suppl):84–105.

[7] Stewart, T. C., Gilliland, J., & Fraser, D. D. (2014). An epidemiologic profile of pediatric concussions: identifying urban and rural differences. *Journal of trauma and acute care surgery*, *76*(3), 736-742.

[8] Johnstone B, Vessell R, Bounds T, Hoskins S, & Sherman A (2003). Predictors of success for state vocational rehabilitation clients with traumatic brain injury. *Arch Phys Med Rehabil; 84*(2):161-7.

[9] Spearman RC, Stamm BH, & Tivis LJ (2007). Traumatic brain injury state planning grant: Preparing for change in a rural state. *Brain Injury; 21*(8).

consideration when it comes to researching TBI.[10] As such, rural disparities in TBI are indicated as an area worthy of exploration within the recent CDC Report to Congress on the Management of TBI in Children.[11]

To this end, CDC's Injury Center is conducting this project to conduct formative research to understand challenges that rural healthcare providers face when diagnosing, treating, and managing TBI. This will allow us to modify our materials for the rural setting and identify areas for future research that will allow us to better understand these challenges and potential ways to address them. CDC is seeking approval from OMB to conduct focus groups with clinicians practicing in rural settings to gather more detailed information on their experiences with the diagnosis, treatment, and management of mild TBI, as well as identify opportunities to address gaps in services. The focus groups will gather respondents' perspectives in a group setting.

The target population for the data collection effort includes physicians, nurse practitioners (NPs), and physician assistants (PAs) in selected specialties (general or family practice, emergency medicine, pediatrics) working in direct patient care in rural areas. A sample of physicians, NPs, and PAs practicing in rural settings will be invited to participate in a focus group about their experiences (**Attachment 8**). The results of this study will inform CDC Injury Center's efforts to improve the implementation of existing clinical guidelines and other resources for healthcare providers, as well as develop educational offerings and programs for rural clinicians.

The proposed information collection is authorized by the Public Health Services Act (PHS Act) which provides the legislative means for states to advance public health across the lifespan and to reduce health disparities. Section 301 (a) of the PHS Act, 42 U.S.C. 241 (a), authorizes grants to aid "other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the cause, diagnosis, treatment, control and prevention of physical and mental diseases and impairments of man" (**Attachment 1**).

A.2. Purpose and Use of Information Collection

The purposes of this study are to (1) Conduct formative research to understand challenges that rural healthcare providers face when diagnosing, treating, and managing mild TBI so that we are able to modify our materials (trainings, dissemination materials, messages, recommendations) for the rural setting and (2) Identify areas for future research that will allow us to better understand these challenges and potential ways to address them. The results of this information collection will inform CDC's immediate and future outreach and education for rural healthcare providers, including:

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[10] Centers for Disease Control and Prevention. (2015). Report to Congress on Traumatic Brain Injury in the United States: Epidemiology and Rehabilitation. National Center for Injury Prevention and Control; Division of Unintentional Injury Prevention. Atlanta, GA. Accessed: https://www.cdc.gov/traumaticbraininjury/pdf/tbi_report_to_congress_epi_and_rehab-a.pdf.

[11] Centers for Disease Control and Prevention. Report to Congress: The Management of Traumatic Brain Injury in Children. Atlanta, GA: National Center for Injury Prevention and Control; Division of Unintentional Injury Prevention,, 2018.

- CDC's "HEADS UP for Healthcare Providers" educational program (https://www.cdc.gov/headsup/providers/index.html)
    - Online concussion training for healthcare providers
    - Tools for providers (e.g. acute concussion evaluation care plans)
    - Discharge instructions
    - Materials for patients (e.g. facts about concussion and brain injury)
    - Return to play management advice
- Recently released pediatric mild TBI guidelines and related materials (https://www.cdc.gov/traumaticbraininjury/PediatricmTBIGuideline.html)
    - Checklist on diagnosis and management
    - At-a-glance sheets on diagnosis, prognosis, and treatment
    - Letters to be filled in by healthcare providers

The ability to tailor these programs and materials specifically to the needs of healthcare providers working in the rural setting will allow them to be more effective and targeted.

The second goal of this information collection request is identify areas for future research in this arena. We expect that the focus group participants will give us new insight into the challenges they face in diagnosing and managing TBI as well as possible ways they have devised to overcome some of these challenges. Additionally, we hope to garner information about the focus group participants' current practice to potentially inform more specific, quantitative studies related to understanding rural providers' TBI practices related to diagnosis and management.

The target population for the data collection effort includes physicians, nurse practitioners (NPs), and physician assistants (PAs) in selected specialties (general or family practice, emergency medicine, pediatrics) working in direct patient care in rural areas. For this study, "rural" will be defined using the 2013 National Center for Health Statistics (NCHS) Urban-Rural Classification Scheme for Counties.[12] In particular, rural counties will be those defined by NCHS as being non-metropolitan (micropolitan or noncore counties). See below for full enumeration of the scheme.

- Metropolitan counties
    - Large central metro counties in MSA of 1 million population that: 1) contain the entire population of the largest principal city of the MSA, or 2) are completely contained within the largest principal city of the MSA, or 3) contain at least 250,000 residents of any principal city in the MSA
    - Large fringe metro counties in MSA of 1 million or more population that do not qualify as large central
    - Medium metro counties in MSA of 250,000-999,999 population.
    - Small metro counties are counties in MSAs of less than 250,000 population.
- Nonmetropolitan counties
    - Micropolitan counties in micropolitan statistical area
    - Noncore counties not in micropolitan statistical areas

[12] Centers for Disease Control and Prevention. (2017, June 1). NCHS Urban-Rural Classification Scheme for Counties. Retrieved from https://www.cdc.gov/nchs/data_access/urban_rural.htm.

This study has one data collection method:

Focus Groups: To gain deeper insight into the context supporting and/or inhibiting access to comprehensive TBI evaluation and treatment, the study will collect qualitative data through focus groups with rural clinicians. The focus group format will allow for more thorough exploration of the key challenges for rural clinicians when managing mild TBIs and identify opportunities for CDC to better support clinicians in rural settings. CDC plans to convene 6 in-person focus groups composed of 8-10 providers each, for a total of up to 60 respondents. If needed, virtual focus groups will be held after the in-person ones if initial recruitment goals are not met. Prior to beginning the focus group, we will ask participants to complete a written questionnaire (**Attachment 7**) that includes questions about the participant's experience, as well as demographic questions including race, ethnicity, and sex.

The data stemming from the focus groups will help to answer research questions that address two key topics: 1) challenges that rural clinicians face in diagnosing and managing TBI, and 2) areas for future research that will allow us to better understand these challenges and potential ways to address them. A cross walk of the research questions and the focus group discussion questions for each topic is provided in Table 1 below.

Table 1. Focus group guide by research question

Key topic: Challenges that Rural Clinicians Face in Diagnosing and Managing Mild TBI	
Focus Group Discussion Question	Purpose
A1. Tell us about the risk of concussion or mild TBI in your patient population. How often do you assess a potential concussion or mild TBI in a month? A2. What are the most common causes of mild TBI and concussion among residents in your community?	These questions will allow us to get a feel for the level of experience among the focus group participants in treating patients who have experienced a TBI.
Research Question: What are the challenges and difficulties faced by rural health care providers in diagnosing and managing/treating TBI?	
Focus Group Discussion Question	Purpose
B2. Do you experience any challenges or difficulties in diagnosing mild TBI? What is the primary challenge you face in diagnosing mild TBI? B3. Are any of these challenges or difficulties unique to diagnosis of mild TBI in children and adolescents?	These are the main questions that are used to assess challenges among the providers. If necessary, we will prompt them to speak about their challenges with equipment, staffing, training, and patient perceptions.
Research Question: What challenges exist for rural providers as they relate to access to services following TBI?	
Focus Group Discussion Question	Purpose
C1. Are patients diagnosed with mild TBI treated and managed within your practice/organization or are they referred/transferred elsewhere? C1i. If patients are treated locally: What challenges or difficulties do you face in treating and managing mild TBI? *(e.g., training, staffing, systems of care, health insurance coverage, etc.)*. How are these challenges managed? C1ii. We're going to discuss patient challenges with follow up care in just a minute. The question we have now is what challenges or difficulties do you experience when referring/transferring these patients? *(e.g., coordination with other providers, sharing information, patient's out-of-pocket costs, health insurance coverage, out of network providers, etc.)*. How are these challenges managed?	These questions will allow us to get insight into whether the providers are able to treat patients with TBI in-house or they have to refer out for more specialized care.
Research Question: What obstacles do rural providers see in their patients/community to either obtaining initial care following a TBI or for getting	

follow-up care?	
Focus Group Discussion Question	Purpose
D1. What, if any, are the patient barriers to obtaining initial care following a mild TBI? D2. What, if any, obstacles do patients face in getting follow-up care following a mild TBI?	These questions will allow respondents to talk about barriers to care that they see among their patients.
Research Question: What processes do rural health care providers and educators engage in to ensure that children return to school and play following a TBI in a way that minimizes academic disruption? What are the unique challenges in managing this process in a rural setting, if any?	
Focus Group Discussion Question	Purpose
E1. Some communities have adopted what are called "return to school" or "return to learn" policies that are meant to help children and adolescents successfully transition back to school after experiencing a concussion or mild TBI. Do your local school districts or does your state have any return to school policies or practices following concussions for children? E1i. If yes, can you tell us about them?	These questions gauges how much the respondents know about their communities' return-to-learn policies. It is possible that their communities have such policies but the providers do not know about them or that their communities have no such policies (both of which would provide an opening for improvement).
E2. Tell us about the processes you go through with children in regard to returning them to school after they have experienced a mild TBI. E2i. What kinds of interactions have you had with parents or educators about returning children to school after experiencing a mild TBI?	These questions are meant to elicit the providers' protocols, if they exist, for ensuring a safe return of students to school following a TBI and whether they coordinate with parents and educators for this process. They could also open up the discussion about challenges that these providers face in doing so, if they do not have a protocol or they have trouble getting the parents on board, for instance.
E3. Tell us about the processes you go through with children in regard to returning them to playing sports after experiencing a concussion. E3i. How do you talk with parents and coaches about this process?	As a companion to E2, these question asks about providers' experience with returning youth to play/sports safely following a concussion. Often this portion is just as important as returning to school for young athletes, and presents unique challenges (for instance, if the child is serious about athletics or has a coach that is pushing for a quick return).
Research Question: What TBI-related information is lacking among rural health care providers?	

Focus Group Discussion Question	Purpose
B1. What tools do you use to diagnose mild TBI?	This question will allow us to see what tools the rural providers use to diagnose TBI; whether they are using up-to-date, evidence-based tools; and how we might be able to convey to them the information they would need to take advantage of these tools.
F2. What mild TBI-related information would be helpful to improve patient knowledge and awareness of TBI in your community?	This question will allow us to directly assess what TBI information these providers think is lacking among themselves and their peers.
Key Topic: Identify areas for future research that will allow us to better understand these challenges and potential ways to address them.	
Focus Group Discussion Question	Purpose
F5. What do you want the CDC to know about mild TBI in rural communities?	This question will allow respondents to speak to any TBI-related issue that is important to them; we hope that responses to this question will expand our view of what's happening on the ground in rural areas and let us know exactly where the challenges and opportunities lie.
Research Question: Which, if any, innovative approaches have rural providers tried or would like to try to overcome these challenges?	
Focus Group Discussion Question	Purpose
B4. How do you manage these challenges?	This is a follow-up question to the general "do you experience any challenges or difficulties in diagnosing/treating/referring" TBI question. B4 will allow the providers to talk about their experience and ideas about managing these challenges, in both typical and innovative ways that might be of use to other rural healthcare providers in similar situations.
Research Question: What resources are needed for rural providers to improve their TBI-related practice, including any training and decision support tools?	
Focus Group Discussion Question	Purpose
A3. How prepared do you feel to diagnose and manage patients with mild TBI with respect to the training you have received, opportunities for your continuing education, and the frequency with which you are	This question will serve as a way for us to learn about challenges and difficulties the providers face in diagnosing and managing TBI in their patient populations. The participants can let us know if they feel

able to treat concussion/mTBI in your patient population?	unprepared, why they might feel this way, and whether training or lack of training plays a role in this feeling.
F1. What mild TBI-related information would be helpful to improve patient knowledge and awareness of TBI in your community? F2. What clinical training/continuing education, if any, would be helpful to improve your mild TBI-related practice? F3. What kind of mild TBI training experiences have you found helpful? These can be informal or formal. F4. What other resources might be helpful to improve your mild TBI-related practice?	These questions directly ask the providers what type of training and experiences they have had in the recent past and what they would like to see in the future to help them improve their TBI practice.

The study will help CDC understand the current clinical practices for the diagnosis, treatment, and management of TBI in rural settings, including the contextual factors that facilitate or inhibit rural clinicians' ability to provide high quality care. Results will inform CDC's future public health efforts, in particular, research and programs regarding TBI that are tailored to the needs of rural clinicians and communities.

Focus group results could also be used to generate research questions that we could test in future quantitative research projects. We plan to conduct a quantitative web-based survey of approximately 600 rural healthcare providers (approximately 150 burden hours) which would allow CDC to gather structured data on the processes and protocols identified in the focus groups that are being used by rural clinicians to assess and treat mild TBI. This web-based survey would provide an opportunity to ask more specific, fine-grained questions that may not come up in the focus group. In addition, focus group results from this study could be used to generate ideas for additional questions or generate ideas for response options that we would not have known about or considered otherwise. For example, focus group participants might identify a unique clinical practice but only quantitative information could give us an idea about how widespread that clinical practice is. Also, focus group participants might identify a particular challenge in managing TBI in the rural setting; a quantitative study could give us a better idea how common that challenge is among a larger sample of rural clinicians. This information, both qualitative and quantitative, could influence CDC's prevention efforts. Further, it would allow us to better adapt educational materials related to recommended clinical practices for rural clinicians.

A.3. Use of Improved Information Technology and Burden Reduction

CDC will collect qualitative data using focus groups; therefore, information technology will not be used to collect data from the individuals recruited to participate in the focus groups. Because the data collection is qualitative in nature and requires information from a relatively small number of individuals, it is not appropriate, practical, or cost-beneficial to build electronic instruments to collect the information. The proposed focus groups will collect only the minimum information necessary for the purposes of the project. However, there are several ways in which the focus groups have been designed to decrease participant burden. First, participation in the focus group will be combined with respondents' attendance at a previously-scheduled conference. No additional travel will be necessary. Second, efforts have been made to design items that are easily understandable, not duplicative in nature, and least burdensome. In all instances, the number of items posed will be held to the minimum required in order to elicit the necessary formative or materials-testing data.

A.4. Efforts to Identify Duplication and Use of Similar Information

Current sources of information about the challenges that healthcare providers in rural areas face when diagnosing and managing TBI do not exist. The work that is currently being done in the area of TBI by the CDC and other federal agencies is distinct from our proposed project. For

example, the Traumatic Brain Injury team at CDC's Injury Center is conducting several TBI projects. We have recently concluded projects that examine states' and individual school and healthcare systems' return-to-school and return-to-play policies and procedures following youth sports concussions. Much of the CDC's TBI work is focused on preventing concussions. For example, the HEADS UP program (https://www.cdc.gov/headsup/index.html) has fact sheets, online training courses, and even a mobile gaming application meant to teach children, parents, coaches, and healthcare providers about concussion safety. Finally, the Traumatic Brain Injury team has also designed a study that aims to validate a case definition for the collection of self-report data that can eventually be used for TBI surveillance OMB# 0920-1240, exp. 08/31/2021 (Traumatic Brain Injury (TBI) Surveillance System).

However, these efforts have aims that are distinct from this proposed project. The aim of the surveillance system described above is to test the validity of a three-tiered case definition designed to assess whether a TBI was sustained during the last 12 months using survey data while the main aim of the HEADS UP program is to prevent concussions from occurring, especially among children and adolescents. The aim of the proposed project described in this package, on the other hand, is to understand the challenges that rural healthcare providers face when diagnosing, treating, and managing TBI. This project will interview healthcare providers who treat patients with TBI while the surveillance system surveys a sample of adults and adolescents, some of whom have experienced a TBI. While it is possible that a future surveillance system could capture information about the burden of TBI in rural areas, our project is unique in that it is focusing specifically on healthcare providers in rural communities. Also, while the surveillance system proposes to capture numbers and percentages for those who have experienced a TBI, this project is looking at the process of TBI diagnosis and management.

Additionally, we conducted a search of the Office of Information and Regulatory Affairs website to determine if other federal agencies have submitted information collection requests for TBI-related projects of which we are not aware. We identified one other recent federal TBI research project in this system. The NIH is currently working on a project entitled "National Institute of Neurological Disorders and Stroke Federal Interagency Traumatic Brain Injury Research (FITBIR) Data Access Request." The project is focused on sharing TBI datasets and does not have a particular focus on either rural communities or healthcare providers. Therefore, through our participation with the National Research Action Plan for TBI and by reviewing the Office of Information and Regulatory Affairs' website on current information collection requests, we are confident that no effort has been undertaken by other federal agencies which closely matches the one we are proposing.

A.5 Impact on Small Businesses or Other Small Entities

It is possible that some participating healthcare providers will be small entities; however, the focus groups will be conducted during national conferences where healthcare providers will already be away from their practices. Therefore the impact and burden will be minimal. This study will not unduly affect small businesses or small entities.

A.6. Consequences of Collecting the Information Less Frequently

The design of this study requires only one data collection activity per respondent. Without collecting this data, CDC will not have adequate information to understand the unique challenges facing rural clinicians in diagnosing, treating, managing, and preventing mild TBI. Therefore, programs and services for rural healthcare providers and patients, such as the Mild Traumatic Brain Injury Guidelines, Online Concussion Training, or sample discharge instructions, developed by CDC may not fully account for these unique challenges, reducing their utility for rural clinicians. The federal government will find enormous benefit in having information available that will answer the questions about how, and to what extent, are current CDC programs regarding TBI being used in rural settings. Additionally, this study will be the first to examine challenges and facilitators in rural settings and provide valuable information for future program development.

A.7. Special Circumstances Related to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A.8.a) Federal Register Notice

A 60-day Federal Register Notice was published in the Federal Register on June 7, 2018, vol. 83 No. 110, and pp. 26464-26465 (**Attachment 2**). CDC received two substantive public comments and replied with a response (**Attachment 3**). Modifications to this study will not be possible under the present budget, sample size needs and timeline. However, public comments will be consider for future studies.

A.8.b) Efforts to consult outside the agency

In order to stay informed about TBI work that is happening outside of the agency, CDC has representation on the National Research Action Plan for TBI, an Executive Order-created workgroup that coordinates federal TBI research and response. In addition to CDC, the federal agencies represented on this group include the Department of Defense, Veterans Administration, National Institutes of Health (NIH), and the National Institute on Disability, Independent Living, and Rehabilitation within the Administration for Community Living of the Department of Health and Human Services. Beyond monthly teleconferences in which projects are discussed, representatives of this group participate in a yearly “Review and Analysis” of all federally-funded TBI-focused projects. The portfolio of TBI-focused projects is presented to higher-level agency representatives as a means to account for the work that has been done and to set direction

for future TBI-focused work. None of the agencies listed above are currently working on assessing the challenges that rural healthcare providers face in diagnosing and managing TBI.

In an effort to consult with experts both inside and outside of the U.S. Department of Health and Human Services, CDC is contracting with NORC to collect and analyze and focus group data. NORC has also partnered with the National Rural Health Association (NRHA) to identify potential focus group participants. NRHA is a national nonprofit membership organization with more than 21,000 members. The association's mission is to provide leadership on rural health issues through advocacy, communications, education, and research. NRHA membership consists of a diverse collection of individuals and organizations, including healthcare providers, all of whom share the common bond of an interest in rural health. NORC is responsible for all data collection activities, including administrative oversight, data collection, and data analysis.

CDC Injury Center's staff reviewed the focus group protocol and provided feedback on the electronic versions of the instruments during conference calls and via email. NORC also sought the input of Yaser B. Freij, MD, a rural physician. Dr. Freij also reviewed the data collection instruments.

A.9. Explanation of Any Payment or Gift to Respondent

There will be no payments or gifts to respondents.

A.10. Protection of the Privacy and Security of Information Provided by Respondents

The Office of the Chief Information Officer at the CDC has determined that the Privacy Act does apply. The Privacy Impact Assessment (PIA) is attached (**Attachment 9**). During data collection, the contractor will have access to personally identifiable information used to contact potential participants to invite them to participate in the focus groups. For the focus groups, personal information is secondary data, previously collected. CDC and the contractor will work with the National Rural Health Association to identify a convenience sample during one or more NRHA national meetings. A SORN is not needed because CDC and the contractor will be contacting participants by using secondary data already collected.

This system collects and maintains names, e-mail address, mailing address, phone number, gender, age, race/ethnicity from physicians, physician assistants, and nurse practitioners living in rural areas. No personal health information will be collected or maintained. Respondents will be assigned a study ID for use on data collection instrument and all data files shared with CDC will be de-identified to maintain the privacy of those who participated in the study. Additionally, data files will be delivered using a secure file transfer protocol (SFTP) site. All data collected from the focus groups will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

Participation in the focus groups will be voluntary for all respondents. Potential participants will be sent information about the study and what is required for participation. The elements of

consent will be explained in these communications (**Attachment 4**). Personally identifiable information (PII), such as the name of the respondent and his/her contact information will not be stored in the initial focus group data files at any time. Unique identifiers will be assigned to each case in the data files as data are collected and participants removed from contact lists when their focus group participation is complete. Focus group data will be stored by the contractor in secure servers.

All respondents will be told during the consent process (**Attachment 6)** that the data they provide will be treated in a secure manner to the extent allowed by law. They also will be informed that participation is voluntary, that they may refuse to answer any question, and can stop at any time without risk. In addition, names of participants in any component of the study will not be provided to the federal government. Instead, a unique ID will be assigned to each participant.

Below is an overview of the steps taken to ensure the privacy of respondents for the focus groups under this request for OMB clearance, including targeted respondents; identifiable information to be collected; parties responsible for data collection, transmission, and storage; and parties with access to the data and uses of the data.

Focus Groups (**Attachment 8**) will include discussions with rural primary care and emergency physicians, nurse practitioners, and physician assistants. Contracting staff will conduct the focus groups. The discussions will be recorded and transcribed (only first names or nicknames of respondents will be collected); all information will be transmitted and stored securely on the contractor's servers. Focus group transcriptions will be uploaded and coded and in a qualitative database, using QSR NVivo software. Key themes will be developed based on the qualitative data analysis. Such identified themes and quotes may be included in reports; specific quotes will not be attributed to any single person in any reports. During the consent process, participants will be made aware that the CDC may report the results of the focus groups in aggregate. They will be informed that their names will not be used with individual responses. Any publications stemming from this data collection will be shared with participants when possible.

Only approved members of the project team will have access to the data collected through the focus groups for the purposes of analysis and reporting. Focus group discussions will be transcribed and coded for analysis. Activities of specific respondents may be mentioned; however, individual respondents will not be identified in any materials. At the end of data collection and analysis, the contractor will securely transmit data to CDC and data will be permanently destroyed on the contractor servers. In addition, original recordings and transcriptions from the focus groups will not be shared with CDC to protect key informant privacy though the database of codes for each observation may be shared with CDC. Upon contract termination and per the terms of the contract, the contractor will archive any data collected as part of the study. CDC will retain and destroy records in accordance with the applicable CDC Records Control Schedule.

The appropriate security controls and Rules of Behavior will be incorporated to protect the security of information and personally identifiable information that the contractor may come in

contact with during the performance of this contract. All data will be stored within the internal contractor's secured file server and will be maintained by the contractor on behalf of CDC. Only approved members of the project team will have access to the data collected. Recordings will not be shared with CDC.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

CDC has received IRB approval for this exempt research activity involving human subjects where CDC is not engaged. NORC has its own IRB, which meets all of the Federal requirements as specified in 45 CFR 46, registered with the Office for Human Research Protections and with Federal Wide Assurance (FWA00000142). This ensures that all of its projects involving human subjects comply with Federal regulations. (**Attachment 10**).

Sensitive Questions

In general, the focus group guide and related questionnaire designed for this data collection effort do not contain sensitive questions about topics such as sexual behavior or drug use. However, for some individuals, demographic questions, including age, sex, race/ethnicity, and geographic location of the respondent, are thought to be of a sensitive nature. This information will help CDC to explore if responses differ based on the demographic characteristics of the healthcare provider. We will use this information to explore whether there are patterns in the qualitative data from the focus groups, to the extent possible, by age, sex, race, ethnicity, and geographic location. We will explain to study participants that these questions are asked for analysis purposes only. Participants may decline to respond to the questions, and they will still be able to participate in the study. The informed consent for the focus groups (**Attachment 6)** explains that participants can refrain from answering any questions. All questions are voluntary in nature. There will be no negative consequences to any respondent, should they choose not to answer one or all of the questions. In the informed consent, we will inform all study participants that all data collected will be treated in a secure manner.

A.12. Estimates of Annualized Burden Hours and Cost

Rural healthcare providers referred from NHRA will be invited by email to participate in the focus groups (**Attachment 4**) and their eligibility will be confirmed with a focus group screener before the focus groups are scheduled (**Attachment 5**).

In order to be recruited for the focus groups, the rural healthcare providers will first need to complete and send back a screener form. We estimate that the screener will take about 3 minutes to complete. While most healthcare providers will be eligible, not all will be, so the screener will be completed by more providers than the rest of the material. During the actual focus group, the participants will be asked to complete a set of 10 demographic and background questions before the discussion begins. We estimate that this will take each participants 5 minutes to complete.

We estimate that reading through and signing the consent will also take 5 minutes. The time needed to complete each focus group discussion is estimated to be 80 minutes. The focus groups will occur during national conferences at which respondents have separately registered to attend. If needed, additional focus groups will be conducted by conference call or webinar. We are planning to conduct this data collection over a two-year time period, therefore the sample numbers for each strata are divided in half.

Table 4. Estimated annualized burden hours

Type of Respondent	**Form Name**	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden (in hours)**
Health care providers (Primary Care Physician, Emergency Physician, Nurse Practitioner and Physician Assistant)	Focus group screener (Att. 5)	34	1	3/60	2
	Focus group consent (Att. 6)	30	1	5/60	3
	Focus group questionnaire (Att. 7)	30	1	5/60	3
	Focus group discussion guide (Att. 8)	30	1	80/60	40
Total					48

Annual Burden Cost

The annualized hour and cost burden is estimated to be $91.58 based on the BLS median hourly wage for family and general practitioners, [13] $99.48 based on the BLS median hourly wage for physicians and surgeons (all other, including emergency physicians),[14] $48.52 based on the BLS median hourly wage for nurse practitioners,[15] and $48.79 based on the BLS median hourly wage for physician assistants[16] as of 2017. The data collection instrument is the same for all respondents. There are no direct costs to respondents associated with this information collection.

The total estimated annualized cost to respondents is $3,745.

Table 5. Estimated annualized burden costs

Type of	**Specific type**	**Form Name**	**No. of**	**Total Burden**	**Hourly Wage**	**Total Cost**

[13] Source: BLS Website, as of December 18, 2017. [https://www.bls.gov/oes/current/oes291062.htm]
[14] Source: BLS Website, as of December 18, 2017. [https://www.bls.gov/oes/current/oes291069.htm]
[15] Source: BLS Website, as of December 18, 2017. [https://www.bls.gov/oes/current/oes291171.htm]
[16] Source: BLS Website, as of December 18, 2017. [https://www.bls.gov/oes/current/oes291071.htm]

Respondents	**of Respondents**		**Respondents**	**(in hrs.)**	**Rate**	
Healthcare Providers	Primary Care Physician	Focus Group Screener	9	1	$91.58	$92
		Focus group consent	8	1	$91.58	$92
		Focus group questionnaire	8	1	$91.58	$92
		Focus group discussion guide	8	11	$91.58	$1,008
	Emergency Physician	Focus Group Screener	7	1	$99.48	$100
		Focus group consent	6	1	$99.48	$100
		Focus group questionnaire	6	1	$99.48	$100
		Focus group discussion guide	6	8	$99.48	$796
	Nurse Practitioner	Focus Group Screener	9	1	$48.52	$49
		Focus group consent	8	1	$48.52	$49
		Focus group questionnaire	8	1	$48.52	$49
		Focus group discussion guide	8	11	$48.52	$534
	Physician Assistant	Focus Group Screener	9	1	$48.79	$49
		Focus group consent	8	1	$48.79	$49
		Focus group questionnaire	8	1	$48.79	$49
		Focus group discussion guide	8	11	$48.79	$537
					Total	$3,745

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

The requested data collection does not impose a financial burden on respondents, nor will respondents incur any expense other than the time spent participating in the focus group. Therefore, there are no additional respondent costs associated with start-up or capital investments. There are also no operational, maintenance, or equipment respondent costs associated with continued participation in the assessment.

A.14. Annualized Cost to the Government

The total two-year cost of the study to the government is $52,672, which includes the amount awarded via contract to NORC for the focus groups ($24,360) and CDC staff time/resources ($28,312). It is estimated that two CDC employees (one GS-13 health scientist and one GS-13 behavioral scientist) will be involved for approximately 10% and 5% of their time, respectively (for federal personnel 100% time = 2,080 hours annually). The two salaries are both $45.37 per hour. The direct annual costs in CDC staff time will be approximately $14,156 annually. The annualized contract cost has been determined to be $26,336 per year by dividing the total funded amount by two years. Data collection and data delivery costs for conducting this project are included in the contract between NORC and the CDC under contract number HHSD2002013M53955B.

Table 6. Annualized Costs to the Federal Government

Agency	Task	Total Cost Amount
Contractor	Develop study design; participant recruitment; focus group discussion guide development; data collection; data analysis; development of report; delivery of data files	$12,180
Government	Oversee study; review all study-related materials, including instruments, consent forms, recruitment materials; liaise with government regulatory entities.	$14,156
Total Annualized Cost		$26,336

The total cost to the government over the two year study period is $52,672.

The CDC is currently engaged in a contract with NORC for data collection and data analysis. The current deliverable and payment schedule states that NORC will begin data collection by May of 2019. Data collection will need to begin by this time in order to avoid modification to the contract and potentially additional costs to the government.

A.15. Explanation for Program Changes or Adjustments

This is a new information collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

16.1 Time schedule

Table 7 below shows the timeline after OMB approval.

Table 7. Project Timeline

Activity	Schedule
Data Collection	1 – 24 months after OMB approval
Focus groups	1 – 24 months after OMB approval (pending conference dates)
Data Analysis	13 – 24 months after OMB approval
Reporting	24 months after OMB approval

Data analysis will focus on identifying results of the key research questions.

The qualitative analysis will focus on the open-ended questions from the focus groups. We will conduct qualitative analysis using the NVivo 11 software. We will utilize a theme-based approach to analyzing qualitative data, guided by the research questions, specifically focusing on the facilitators and barriers identified by rural healthcare providers in diagnosing, treating, referring, and managing TBI.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification statement.