

**GenIC Clearance for CDC/ATSDR  
Formative Research and Tool Development**

**Title: *Formative Testing of CDCs Mild Traumatic Brain Injury and Concussion  
Discharge Instructions for American Indian and Alaska Native Adult Patients***

**Request for GenIC Approval**

Contact Information:

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**PROJECT TITLE: *Formative Testing of CDCs Mild Traumatic Brain Injury and Concussion Discharge Instructions for American Indian and Alaska Native Adult Patients.***

**PURPOSE AND USE OF COLLECTION:**

The information collected for this qualitative formative testing will be used to inform CDC's efforts to understand information gaps among AI/AN adults and obtain information about the suitability (e.g., clarity, applicability) of current adult patient mild TBI and concussion discharge materials from Tribal Health Care Providers, Tribal leaders, and AI/AN adults from urban and rural areas. Research from this study will help CDC's DIP effectively provide updates to CDC's discharge instructions to better meet the needs of AI/AN adults and develop a dissemination plan to enhance outreach to AI/AN adults in rural and urban areas.

Each Tribal Healthcare Provider will need to complete one eligibility screener (ATTACHMENT 2) and participate in one in-depth interview (ATTACHMENT 7). The eligibility screener contains 11 questions. The in-depth interview guide consists of 22 questions.

Each Tribal Leader will need to complete one eligibility screener (ATTACHMENT 3) and participate in one in-depth interview (ATTACHMENT 8). The eligibility screener contains 13 questions. The in-depth interview guide consists of 20 questions.

Each AI/AN Adult will need to complete one eligibility screener (ATTACHMENT 1) and participate in one focus group discussion (ATTACHMENT 6). The eligibility screener contains 12 questions. The focus group discussion guide consists of 20 questions.

**DESCRIPTION OF RESPONDENTS:**

The potential respondent universe for this proposed information collection includes Tribal Health Care Providers, Tribal Leaders, and American Indian/Alaska Native (AI/AN) Adults, aged 18 years and older. Individuals within these groups will be recruited via two approaches:

1. We will use a recruitment firm to recruit any final hard-to-reach populations.
2. We will identify partners that focus on serving AI/AN communities (e.g., the Indian Health Service and National Tribal Epidemiology Centers) and leverage the partnership to recruit individuals by sharing recruitment materials with organizational leaders with influence.

All recruitment materials will be in English (ATTACHMENTS 1 through 7). They will include information on the purpose of the data collection, eligibility requirements, contact information for additional questions, and a link to a screening survey for individuals to express their interest in participating.

| Method | Sample Eligibility Criteria & Number of Screener Questions | Sample Research Questions & Number of Data Collection Questions |
|--------|------------------------------------------------------------|-----------------------------------------------------------------|
|--------|------------------------------------------------------------|-----------------------------------------------------------------|

|                                       |                                                                               |                                                                                                                                                                                    |
|---------------------------------------|-------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| In-Depth Qualitative 1-On-1 Interview | Tribal Leaders<br>13 Questions                                                | “Overall, what do you see as the main purpose of the discharge instructions, in your own words?”<br><br>20 Questions                                                               |
| In-Depth Qualitative 1-On-1 Interview | Health Care Providers that serve Tribal communities or people<br>11 Questions | “In reviewing the discharge instructions, was there anything in them you found confusing, unclear, or hard to understand?”<br><br>22 Questions                                     |
| Qualitative Focus Group Discussion    | AI/AN Adults aged 18 and over<br>12 Questions                                 | “If you were a patient with a mild traumatic brain injury or concussion would you review these discharge instructions with family or friends? Why or why not?”<br><br>20 Questions |

#### **CERTIFICATION:**

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. Information gathered will not be used to substantially inform influential policy decisions.
5. The study is not intended to produce results that can be generalized beyond its scope.

Name:     Alexis Peterson    

To assist review, please answer the following questions:

#### **Personally Identifiable Information:**

1. Is personally identifiable information (PII) collected? [ ] Yes [ X ] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [ ] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [ ] No

#### **Gifts or Payments:**

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ X ] Yes [ ] No

Each focus group and interview participant will receive \$50 as a token of appreciation and reimbursement for opportunity costs and expenses (i.e., babysitter, loss of work) incurred due to participation. Providing incentives to respondents is necessary to successfully recruit individuals. All participants are part of a hard-to-reach population. Research suggests that incentives have proven helpful in recruitment of hard-to-reach groups (Bonevski et al. 2014; George et al. 2014). Incentives can increase the likelihood of obtaining a diverse sample of participants, which would include individuals in hard-to-reach and minority populations who encounter complex social

problems that place limitations on their desire and time to volunteer for research studies (Ellard-Gray et al. 2015; Knoll et al. 2012). Literature also reveals the payment of incentives can provide significant advantages to the government in terms of direct cost savings and improved data quality. It also should be noted that message testing is a marketing technique, and it is standard practice among commercial market researchers to offer incentives as part of respondent recruitment.

CDC will apply a health equity lens when selecting our recruitment sample, prioritizing populations that are hardly reached by CDC or concussion prevention information. DIP has had difficulties recruiting sufficient samples of these subpopulations in previous messaging projects. Having insufficient representation from this subgroup means their perspectives are not adequately included in message development which results in less effective messaging to support DIP's goals. An appropriate incentive improves the chances that these subgroups will engage and participate, therefore increasing the government's efficiency in data collection and reducing redundancies for future efforts.

These subgroups have been difficult for DIP to reach for several reasons.

1. For rural AI/AN communities, the social economic situation makes it harder for individuals to utilize PTO or miss work to participate in such projects. Though the data collection will be virtual, low-income populations are less likely to have jobs with remote flexibility, and may have to miss or leave work in order to participate. An appropriate token of appreciation may address this issue.
2. AI/AN subgroups who are being asked to participate are historically less likely to participate in research activities due to mistrust in the medical system fostered by research institutions. Offering a higher token of appreciation addresses health equity issues brought on by historically unjust research practices, by encouraging participation from a more diverse pool of participants.

## BURDEN HOURS

**Table 1. Estimated Annualized Burden Hours**

| Types of Respondents                                          | Form Name                                                         | No. of Respondents | Average Burden per Response (hour) | Total Burden (in minutes per hour) |
|---------------------------------------------------------------|-------------------------------------------------------------------|--------------------|------------------------------------|------------------------------------|
| Tribal Health Care Providers, Tribal Leaders and AI/AN Adults | Screening survey for focus groups and interviews <b>(Att. #1)</b> | 64                 | 8/60                               | 9                                  |
|                                                               | Email AI/AN Adults for focus groups <b>(Att. #2)</b>              | 32                 | 3/60                               | 2                                  |
|                                                               | Follow-up email AI/AN Adults <b>(Att. #3)</b>                     | 32                 | 3/60                               | 2                                  |
|                                                               | Email Tribal Health Care Providers <b>(Att. #4)</b>               | 16                 | 3/60                               | 1                                  |
|                                                               | Follow-up email Tribal Health Care Providers <b>(Att. #5)</b>     | 16                 | 3/60                               | 1                                  |
|                                                               | Email Tribal Leaders <b>(Att. #6)</b>                             | 16                 | 3/60                               | 1                                  |
|                                                               | Follow-up email Tribal Leaders                                    | 16                 | 3/60                               | 1                                  |

|       |                                                                                 |    |   |           |
|-------|---------------------------------------------------------------------------------|----|---|-----------|
|       | (Att. #7)                                                                       |    |   |           |
|       | Focus group discussion guide<br>AI/AN Adults (Att. #8)                          | 32 | 1 | 32        |
|       | Interview guide Tribal Health Care<br>Providers and Tribal Leaders (Att.<br>#9) | 32 | 1 | 32        |
| Total |                                                                                 |    |   | <b>81</b> |

**FEDERAL COST:** The estimated annual cost to the Federal government is \$123,723.38

**If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:**

**The selection of your targeted respondents**

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?

[ X ] Yes [X] No

This information collection request does not employ advanced statistical methods. CDC staff consulted are in DIP and include: Kelly Sarmiento, MPH; Jill Daugherty, MPH, PhD; Alexis Peterson, PhD; and Graham Kirkland, MA. These staff were consulted about the methodological design of the study. Their recommendations were incorporated into the study design and instruments on an ongoing basis. Banyan Communications staff will be responsible for overseeing and executing the data collection and analysis, and these staff are listed below.

**Collaborators**

| Name                               | Organizational Unit                |
|------------------------------------|------------------------------------|
| Nora Kuiper, MPH, Project Director | Banyan Communications (contractor) |
| Chloe Cahill                       | Banyan Communications (contractor) |
| Darola Cherenfant                  | Banyan Communications (contractor) |

**Administration of the Instrument**

1. How will you collect the information? (Check all that apply)

[ ] Web-based or other forms of social media

[ ] Telephone

[ ] In-person

[ ] Mail

[X ] Other, Explain

A combination of Focus Group Discussions (FGDs) and In-Depth Interviews (IDIs) will be used to collect information

2. Will interviewers or facilitators be used? [ X ] Yes [ ] No

#### References

Bonevski, B., Randell, M., Paul, C., Chapman, K., Twyman, L., Bryant, J., Brozek, I., & Hughes, C. (2014). Reaching the hard-to-reach: a systematic review of strategies for improving health and medical research with socially disadvantaged groups. *BMC Medical Research Methodology*, 14, 42. <https://doi.org/10.1186/1471-2288-14-42>

George, S., Duran, N., & Norris, K. (2014). A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders. *American Journal of Public Health*, 104(2), e16-e31.

Ellard-Gray, A., Jeffrey, N. K., Choubak, M., & Crann, S. E. (2015). Finding the Hidden Participant: Solutions for Recruiting Hidden, Hard-to-Reach, and Vulnerable Populations. *International Journal of Qualitative Methods*, 14(5), 1609406915621420. <https://doi.org/10.1177/1609406915621420>

Knoll, M., Soller, L., Ben-Shoshan, M. et al. The use of incentives in vulnerable populations for a telephone survey: a randomized controlled trial. *BMC Res Notes* 5, 572 (2012). <https://doi.org/10.1186/1756-0500-5-572>