GenIC Clearance for CDC/ATSDR Formative Research and Tool Development

In-Depth Interviews about Infection Prevention and Control Practices in Long-Term Care Facilities

OMB Control No. 0920-1154

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Supporting Statement A

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- **Goals of the project:** Understand the knowledge, attitudes, behaviors, and experiences related to infection prevention in long-term care facilities among residents and their family or close friends, to ensure CDC communications clearly and effectively convey information about prevention and control practices intended for residents and their caregivers.
- **Intended use of the resulting data:** Refine and improve the effectiveness of communications materials drafts prior to publication and potential dissemination to long-term care facilities, their residents, and their residents' caregivers.
- Methods to be used to collect data: In-depth interviews.
- **The subpopulation to be studied:** Residents of long-term care facilities, including nursing homes and skilled nursing facilities, and family members or close friends who regularly visit the residents and discuss their health needs and decisions.
- How data will be analyzed: Descriptive and thematic analyses of qualitative data.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is requesting approval for a new generic information collection (gen-IC) under OMB Control No. 0920-1154: "In-Depth Interviews about Infection Prevention and Control Practices in Long-Term Care Facilities."

Information collection activities are limited to formative work that will result in the refinement and improvement of communications materials drafts prior to publication and potential dissemination to long-term care facilities, their residents, and their residents' caregivers.

In this project, both residents of long-term care facilities and their family members or close friends will be interviewed to understand their knowledge, attitudes, behaviors, and experiences related to infection prevention in long-term care facilities, in order to ensure CDC communications clearly and effectively convey important health information to target audiences about both how to prevent infections and why long-term care facilities implement their health protocols.

This project is being proposed by the Division of Healthcare Quality Promotion (DHQP) within CDC's National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). The mission of DHQP is to protect patients and healthcare personnel and to promote safety, quality, and value in both national and international healthcare delivery systems. Two important DHQP priorities in service of this mission are to (1) provide leadership, expertise, and assistance to partners on healthcare safety topics; and (2) to detect, prevent, and respond to healthcare-associated infections and antimicrobial resistant infections.¹

As part of its mission, DHQP works to communicate important information that both professionals and the public can use to stay safe and prevent infections in *long-term care facilities* such as nursing homes and skilled nursing facilities.

According to CDC, individuals who live in a long-term care facility have a higher risk of getting an infection.² Due to residents' close living proximity and often fragile health and advanced age, the health impacts of infections are also serious. The COVID-19 pandemic is a recent example of the risks posed by infections in these settings, as long-term care facilities became "hot spots" during the pandemic.³ But commonplace infections can also spread quickly and have serious negative consequences in these settings. Even when infections are able to be treated, the frequent and use of antimicrobial drugs is a contributing factor in the spread of antimicrobial-resistant infections that have evolved to defeat the drugs designed to kill them.⁴ Additionally, infections among long-term care facility residents that require hospitalization introduce new risks of other serious infections like sepsis, which is "among the most common diagnoses among residents transferred to the hospital from long-term care facilities."⁵

The aforementioned factors are the rationale for this newly proposed interview project. DHQP will use the findings from interviews with residents and their family members or close friends to

¹ "About Division of Healthcare Quality Promotion" https://www.cdc.gov/ncezid/divisions-offices/about-dhqp.html

² "Infection Prevention and Long-term Care Facility Residents" https://www.cdc.gov/long-term-care-facilities/about/index.html

³ Yang, Haoyue et al. "COVID-19 in Long-Term Care Facilities: A Rapid Review of Infection Correlates and Impacts on Mental Health and Behaviors." HERD vol. 15,3 (2022): 277-294. doi:10.1177/19375867221092149

⁴ van Buul, Laura W et al. "Antibiotic use and resistance in long term care facilities." *Journal of the American Medical Directors Association* vol. 13,6 (2012): 568.e1-13. doi:10.1016/j.jamda.2012.04.004

⁵ Yoshikawa, Thomas T et al. "Sepsis in Older Adults in Long-Term Care Facilities: Challenges in Diagnosis and Management." *Journal of the American Geriatrics Society* vol. 67,11 (2019): 2234-2239. doi:10.1111/jgs.16194

refine and improve the effectiveness of communications materials drafts prior to publication. The specific motivation to learn from the resident and family audience directly is to ensure that future communications about infection prevention and control are framed and explained in ways that are comprehensible, personally resonant, and believable to the ultimate audience most at risk of infections in these settings—residents themselves.

CDC has not previously conducted a project or other data collection of this kind among this audience, nor are other studies available from which to draw insights. A combination of factors make this project unique: the qualitative nature of direct interviews with residents; the intent to learn from organic exchanges between each resident and a family member or close friend who shares health decision-making responsibilities; and the specific areas of inquiry related to assessments of their facilities, their experiences there, and their knowledge gained through facility-provided education. These factors represent important gaps in CDC knowledge about the lived experiences and attitudes of residents in these settings.

This data will allow NCEZID to refine and improve the effectiveness of communications materials drafts prior to publication and potential dissemination to long-term care facilities, their residents, and their residents' caregivers.

2. Purpose and Use of Information Collection

The goal of this project is to understand the behaviors, knowledge, and attitudes about infection prevention in long-term care facilities among residents and their family (or close friends). Findings will be used to ensure CDC communications clearly and effectively convey information about prevention and control practices intended for the same resident and caregiver audiences. Findings will aid in the refinement and improvement of communications materials drafts, such as website content, fact sheets, or explanations of protocols, prior to their publication and potential dissemination to long-term care facilities, their residents, and their residents' caregivers.

This data collection will be executed in two related parts: (1) up to 18 online joint interviews between an interviewer and both a long-term care facility resident and the resident's family member (or close friend), lasting 45 minutes each, and (2) up to 18 online follow-up interviews with the same resident's family member (or close friend) alone, lasting 15 minutes each.

KRC Research, a firm contracted to work with NCEZID, will conduct all data collection related to this proposed formative project under NCEZID's supervision. KRC's activities will include recruiting and screening participants into the project, conducting in-depth interviews, and analyzing and reporting on results. This is a one-time data collection that will not be repeated.

The need for this data collection arises from the importance of ensuring NCEZID's infection prevention and control protocols and reasons for them are clear, understandable, and actionable; effectively convey information; and convey the *right* information with an appropriate level of detail among intended audiences. The interviews are formative and designed to understand the baseline knowledge, attitudes, and beliefs about infection prevention and control practices that are specific to long-term care. In contrast, if the data were not collected, communications materials would be published without gathering feedback from the target audience to confirm

they work as intended, which may result in a suboptimal use of government resources and ineffective efforts to combat infections in these high-risk settings.

This data collection involves three instruments: a combined screener (Attachment 1) and joint resident and family member (or close friend) interview guide (Attachment 4), and a follow-up family member (or close friend) interview guide (Attachment 5).

The screener is designed to ensure the participants recruited for interviews meet the criteria and parameters established by NCEZID when evaluating the priority audiences for the communications materials. The screener will be administered by KRC Research and its recruiting team to ensure respondents (a) qualify for participation and (b) represent a variety of geographies, long-term care setting types, and other characteristics. In this project, participants include both residents of long-term care facilities and their family members or close friends who visit often and discuss resident health needs and decisions.

Once a participant has been recruited and scheduled for an interview, a trained KRC Research interviewer will use the interview guide to facilitate the conversation. The guide has been jointly developed by NCEZID and KRC and will be used to ensure the interview covers key areas of inquiry and allocates appropriate time to different topics. In this project, the interview guide includes questions designed to elicit, among other topics:

- Knowledge and attitudes about germs and infections (generally)
- Knowledge, attitudes, and experiences about infection control practices in long-term care facilities
- Extent of education and information received about infection control practices in longterm care facilities, and assessment of that education and information
- Infection prevention considerations as part of evaluating a potential and a current facility
- Information sources, reasons for trusted sources, and communication preferences

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via online interviews through a web-based platform, meaning that participants will not have to download anything to their personal devices (participants need only to have an internet connection). All interviews will be conducted by professional moderators from KRC Research, a contracted company. All interviews will be audio and video recorded to ensure participant responses are captured accurately and transcribed. Questions included on the interview moderator guide have been limited to only those relevant to the target audience to reduce burden on respondents.

4. Efforts to Identify Duplication and Use of Similar Information

NCEZID has not conducted previous qualitative data collections on this topic among this audience. Some other previous studies have been conducted about attitudes and experiences of healthcare professionals involved in long-term care facility infection prevention, but the present proposed study is focused on a different audience: residents and their families. Other previous studies have also been conducted to quantify the prevalence of infections in long-term care

facilities, but those studies are do not assess resident knowledge, attitudes, and understanding about the topic of specific infection prevention protocols. The present proposed study is wholly original in format, design, and specific areas of inquiry; it is designed to fill important gaps in understanding about the target audience. As such, this is an entirely new data collection.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

The screener and the interviews are both one-time information collections.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with the guidelines in 5 CFR 1320.5 and will be voluntary.

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

A. This information collection request does not require publication of a 60-day notice in the *Federal Register*.

B. KRC Research, a contracted firm, has been consulted in the development of the project plan, sampling parameters, and interview guides. Under the supervision of NCEZID, KRC will ultimately conduct all data collection related to the proposed project. Data collection will include recruiting and screening participants into the formative research and conducting up to 18 45-minute-long online joint interviews with a long-term care facility resident and a family member or close friend, followed by up to 18 15-minute-long follow-up interviews with the same family member or close friend alone.

9. Explanation of Any Payment or Gift to Respondents

Interview participants will receive a monetary incentive of \$75 for their participation. Such an incentive is a standard practice in the market research industry and helps to ensure efficient recruitment and ultimate participation among the qualified and scheduled participants. The amount is also standard for participation in interviews of an hour or less. The incentive is also intended to offset the cost of personal or professional time taken to participate.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

NCEZID has determined that the Privacy Act does not apply to this information collection. KRC Research, a contracted firm, will manage recruitment and interviewing for this initiative, and PII will not be transmitted to NCEZID.

The screening instrument for this evaluation is provided in Attachment 1. This screening instrument will be used to evaluate the qualification of potential interview participants. The screening instrument includes information about privacy and confidentiality; only those individuals who agree to these terms will qualify for participation in interviews. After an individual agrees to the terms and has qualified for interview scheduling, they will be given a separate consent form that reiterates privacy and confidentiality policies. Each participant will be required to sign the form (electronic submission is allowed) and deliver a copy to the recruiting and interviewing team. The participants will be reminded that participation is entirely voluntary.

After the consent forms (Attachments 2 and 3) are signed, participants will confirm their interview slots for both the joint resident-family member (or friend) interview and the follow-up family member only interview. During the introduction to each interview, the trained interviewer will review key parts of the privacy and confidentiality agreement:

- 1. The discussion is completely voluntary. Participants do not have to answer any questions they are not comfortable with.
- 2. Only first names or preferred names will be used during the conversation, and nothing participants say or do will be reported in association with their names.
- 3. Discussions will be audio and video recorded and notes will be taken during the discussion. All information, notes, and files will be kept on a secure server. Only KRC Research and the core NCEZID team that manages the evaluation will have access to these files. Files will be deleted within 30 days of NCEZID approval of the final report of findings.

No participants' personally identifiable information will be shared or made available to NCEZID. No recordings will be shared (audio or video), and shared transcripts will have names and any other identifiable information redacted. All findings will be reported in aggregate only.

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

Institutional Review Board (IRB)

This project was reviewed by NCEZID's human subjects advisor and determined to not meet the definition of research under 45 CFR 46. IRB review is not required (Attachment 6).

Justification for Sensitive Questions

The screener (Attachment 1) asks for three <u>optional</u> points of information about long-term care residents that may be interpreted as sensitive: whether a resident has any wounds; whether a resident has any indwelling medical devices (e.g., a urinary catheter, feeding tube, or tracheostomy "breathing" tube); and whether a resident has been placed in isolation at their long-term care facility.

Despite the sensitivity of these questions, they are very important for the project to team to understand as context for all respondent knowledge, attitudes, and experiences related to the core topic of infections and infection prevention. Knowing this information will ensure that respondents' answers are placed in the context of their risk and history for infection (which

varies significantly depending on wounds, indwelling medical devices, and history of facility isolation). These questions are <u>optional</u> and do not preclude a candidate from participating in the interviews if they otherwise qualify.

All other questions asked in the interviews will be non-sensitive in nature and focus on knowledge, attitudes, and experiences about infection prevention largely in the context of the residents' long-term care facility. Participants will be informed that they need not answer any question that makes them feel uncomfortable or that they do not wish to answer.

12. Estimates of Annualized Burden Hours and Costs

The total estimated burden is 63 hours (rounded). Table 1 below describes the burden associated with the information collection.

The burden table reflects the fact that screening questions for <u>both</u> the long-term care facility residents and their paired family member or close friend will be answered by the family member or close friend only, on both individuals' behalf.

Details reflected in the table:

- Only the family/close friend audience will participate in the screening questions (10 minutes)
- Both audience—residents and the family/close friend—will participate in the joint interviews (45 minutes)
- Only the family/close friend will participate in the follow-up interviews (15 minutes)

The burden table assumes that ten respondents will be asked the screening questions for each one that is successfully recruited and scheduled along with the long-term care facility resident for an interview. This one in ten rate is relatively efficient because recruitment is conducted from within a panel of individuals already opted in surveys, focus groups, and interviews. Each individual also has a preexisting demographic profile that makes targeting recruitment much more efficient.

Table 1. Annualized Burden (total burden hours rounded)

Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response (Hours)	Total Burden Hours
Screener (Attachment 1)	Family/close friend	180	1	10/60	30
Interview Guide: Resident and	Long-term care facility resident	18	1	45/60	14
Family/Close Friend (Paired Interview)	Family/close friend	18	1	45/60	14

(Attachment 4) Interview Guide: Family/Close Friend (Follow-Up Interview) (Attachment 5)	Family/close friend	18	1	15/60	5
Total					63

The total estimated cost burden of this information collection is \$1,455.93.

The cost burden has been calculated using the median hourly wage for all U.S. occupations, according to the latest May 2023 National Occupational Employment and Wage Estimates from the U.S. Bureau of Labor Statistics. The median hourly wage for all occupations is \$23.11. The use of this wage rate reflects that the participating populations are essentially adult members of the general public whose specific occupations and range of employments are difficult to predict precisely prior to recruitment.

Table 2. Cost burden associated with information collection (total burden hours rounded)

Form Name	Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Screener (Attachment 1)	Family/close friend	30	\$23.11	\$693.30
Interview Guide: Resident and Family/Close Friend	Long-term care facility resident	14	\$23.11	\$323.54
(Paired Interview) (Attachment 4)	Family/close friend	14	\$23.11	\$323.54
Interview Guide: Family/Close Friend (Follow-Up Interview) (Attachment 5)	Family/close friend	5	\$23.11	\$115.55
Total			-	\$1,455.93

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

There will be no direct costs to the respondents other than their time to participate in each information collection.

14. Annualized Cost to the Government

The annualized cost to the Federal Government to collect this information is \$52,061.28. Table 3 below describes the cost in more detail.

Recruiting and interviewing will be conducted by KRC Research, a contracted firm. KRC's work includes project management, recruitment, screening, scheduling, management of consent forms, conducting interviews, transcription and data cleaning, reporting, and presentation. Contractor

costs cover the work of an existing team working with NCEZID on this and other communications initiatives and include 50 hours of labor for KRC Vice President-level staff, 71 hours of labor for KRC Director-level staff, 96 hours for KRC Analyst-level staff, and 25 hours for a Field Director (recruitment management). Hours are tabulated based on existing contractor hourly rates. Contractor expenses are based on competitively bid prices for panel recruitment / screening and transcription, plus cost of incentives.

Oversight and review of all materials and reports will be conducted by one GS-13 federal government employee who is co-leading the project. Their work will include providing oversight to KRC Research on the purpose and objectives of the project; guidance and feedback on recruitment, screening, and interview guide materials; entering the project materials into CDC's STARS system for project determination; meeting regularly with KRC Research staff to discuss the project's progress and answer any questions; reviewing the transcripts and reports; and sharing topline findings with NCEZID staff so they can use the findings to strengthen communication messages. The estimate includes 20 hours for the Health Communication Specialist.

Estimated federal employee cost is tabulated based on the employee's current hourly wage (locality-adjusted GS pay table for Atlanta-area workers):

• Health Communication Specialist 1: 20 hours @ \$57.60/hour = \$1,152.00

Table 3. Estimated Annualized Cost to the Government per Activity

Cost Category	Estimated Annualized Cost
Contractor personnel costs: costs to oversee recruit, conduct interviews	\$22,261.98
Contractor personnel costs: costs to report on results	\$13,047.30
Contractor expenses: recruitment, transcription, incentives	\$15,600.00
Federal government personnel costs: oversight, report review	\$1,152.00
Total	\$52,061.28

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

This initiative is expected to take eight weeks from start to finish. Five weeks will be spent recruiting and interviewing, and three weeks will be spent in analysis and reporting. A timeline is in Table 4.

Table 4. Project Time Schedule

Activity	Time Schedule
Recruit interview participants	3 weeks, beginning immediately after gen-IC
	approved
Conduct interviews	2 weeks, following recruitment
Transcription, analysis, and report	3 weeks, following completion of interviews
Disseminate results/reports	As soon as summary report is approved

Interviews will be audio and video recorded for aid in reporting and analysis. Audio files will be transcribed verbatim in Microsoft Word and used for reporting. (Deidentified transcripts will be delivered to NCEZID.) Results will be used to develop a written report with an assessment of findings, recommendations for the optimization of infection prevention and control communications, and considerations for potential future NCEZID communications intended for long-term care facilities and their residents and staff.

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to the Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments

- 1. Screener
- 2. Consent Form: Resident
- 3. Consent Form: Family/Close Friend
- 4. Interview Guide: Resident and Family/Close Friend
- 5. Interview Guide: Family/Close Friend Follow-Up
- 6. Human Subjects Determination