Attachment 5 - Step-by-Step How to Use the Generic Clearance for Poison Center Collaborations for Public Health Emergencies

To conduct a Poison Center investigation:

1. After an emergency event is identified, the NCEH project officer reviews the "Step-by-Step How to use the Generic Clearance" guide (**Attachment 5**) and notifies the NCEH/ATSDR ICR Liaison (ICRL) of a potential poison center GenIC.
2. NCEH engages AAPCC to determine if the incident is an eligible public health emergency and ensures all data collection criteria are met (refer to Section A2).
3. Following concurrence from AAPCC, NCEH requests poison center(s) to collect follow-up information.
4. If a 72 or 24-hour approval will be requested, the NCEH project officer prepares and routes the Advance Notification Email with justification (**Attachment 6**) to the ICRL to provide as much advance warning as possible that the request is being prepared. This step is not needed for a 5-day approval.
5. The ICRL routes the 72 or 24-hour advance notification to the CDC Information Collection Request Office (ICRO), which in turn alerts the United States (US) Department of Health and Human Services (HHS) and the OMB desk officers to expect a new urgent poison center GenIC. Again, a 5-day approval will not require advance notification.
6. The NCEH project officer prepares and submits the GenIC package to the ICRL, which includes:
    a. GenIC Request for Approval (**Attachment 7**)
    b. Supporting Statement B
    c. Consent Form (**Attachment 8** - sample consent forms)
    d. Questionnaires (**Attachments 9-11** – sample questions that can be quickly modified)
    e. Worksheet 2
    f. GenIC NCEH Research Determination
    g. Any other supporting documents
7. The NCEH/ATSDR ICRL reviews and submits the GenIC package to ICRO for processing with HHS and OMB.
8. The OMB desk officer responds with approval or comments on the proposed investigation within the time frame is requested (default is 5 days unless otherwise requested).
9. The OMB desk officer may provide approval and comments orally (followed by e-mail for written documentation) or e-mail directly. This may occur before the GenIC request is submitted and received by OMB through the official ICR tracking system.
10. Data collection proceeds upon approval and may not exceed 60 days.

11. Within 5 days of the completion of the data collection, the investigators submit the final data collection instrument(s), consent forms, and associated burden using the "Burden Memo" form (**Attachment 12**) to the ICRL.
12. On a quarterly basis, the ICRL will submit a non-substantive change request for all GenICs conducted in the prior quarter. The following documents will be submitted to support the request: burden memos, final questionnaires, and final consent forms.

The NCEH/ATSDR PRA coordinator serves in the role of the ICRL. The ICRL oversees the clearance process for individual GenICs.

The NCEH program will maintain a library of data collection instruments that includes all final data collection instruments conducted under this Generic ICR.

Questions or Comments? Contact the Poison Center Information Collection Request Liaison (ICRL):

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