Attachment C. Step-by-Step How to Use the Generic Clearance for Emergency Epidemic Investigations (EEI)

Step-by-Step How to Use the Generic Clearance for Emergency Epidemic Investigation (EEI) Data Collections[1]

To conduct an EEI with more than 9 non-Federal participants, follow these steps:

1. Review the EEI Data Collections Generic ICR OMB Package (OMB No. 0920-1011) and Frequently Asked Questions.
2. If you have questions about whether your proposed investigation meets the criteria for an EEI, please contact the EEI Information Collection Request Liaison (ICRL). The ICRL in most cases will be the PRA Contact for the CIO that is requesting the EEI or the Information Collection Review Office (ICRO) Lead.
3. Complete the "Request for Approval Under the Generic Clearance of Emergency Epidemic Investigation Data Collections" form.
4. E-mail the following to the ICRL:
    - Completed "Request for Approval Under the Generic Clearance of Emergency Epidemic Investigation Data Collections" form
    - Letter of invitation from the local, state, or international health authority. (Sensitive information in the Letter of Invitation not appropriate for public dissemination should be redacted prior to sending.)
    - All draft versions of the information collection instruments to be used.
    - The research determination letter (if the investigation is determined to be research)[2]

    If the request is sent outside business hours and immediate approval is needed, notify the ICRL by phone that the request has been submitted.
5. The ICRL will review the request and determine whether it meets the criteria for the Generic EEI Data Collections clearance. If the request meets the criteria, the ICRL will submit the request to the CDC Information Collection Review Office for OMB approval.
6. CDC staff may deploy and begin planning the investigation once the request is submitted to OMB.
7. Data collection cannot begin until OMB has approved the information collection or until 72 hours after OMB was notified of the investigation.
8. The investigation lead or designee must be available to respond to questions about the investigation during OMB's 72 hour review period.
9. Upon receiving OMB approval, ICRL will notify the program and data collection may proceed for up to 90 days.
10. On the cover or first page of <u>each</u> data collection instrument, include the OMB Control No. and Expiration Date (Form Approved, OMB Control No. 0920-1011; Expires: XX/XX/XXXX) in the upper right corner and the public reporting burden statement in the footer. The public reporting burden statement must include the burden estimate for each instrument.
    - See example "Data Collection Instrument Cover Page" [add hyperlink] for placement and language.
11. Prior to data collection, investigators must inform respondents that participation is voluntary, that respondents will not be personally identified in any published reports of

the study, and that their privacy will be protected to the extent allowed under federal law.

12. Within 5 business days of the completion of data collection, submit to the ICRL (via e-mail and interoffice mail) a final copy of all data collection instrument(s) and the completed "Burden Memo."

[1] Additional steps must be taken if the investigation will be an Epi-Aid. To request approval for an Epi-Aid, please contact Danice Eaton (dhe0@cdc.gov; 404-498-6389) or the EIS office main line, 404-498-6110.

[2]A research determination and IRB clearance, if necessary, are the responsibility of the sponsoring Center.

Questions or Comments?
Contact Danice Eaton, the EEI Information Collection Request Liaison (ICRL).

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