

Attachment C. Step-by-Step How to Use the Generic Clearance for Emergency Epidemic Investigation (EEI) Data Collections (0920-1011)

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

1. Determine if your investigation requires OMB approval by requesting a PRA Determination from your CIO PRA Contact. If OMB approval is required, proceed to next step.
2. Review the EEI Generic ICR OMB Package and EEI guidance and resources available at: <http://intranet.cdc.gov/ophss/csels/DSEPD/EEI/index.html>.
3. Contact the EEI Information Collection Request Liaison (ICRL) to discuss whether your proposed investigation meets the criteria for an EEI.
4. Complete the “Request for Approval Under the Generic Clearance of Emergency Epidemic Investigation Data Collections” GenIC form.
5. Identify data collection instruments to be used or modified for the investigation. These can be instruments used in a previous, similar investigation and do not have to be in final form. Each GenIC must include at least 1 data collection instrument.
6. In the GenIC form, for each planned data collection, indicate if a data collection instrument is identified or if it will be developed in the field. Refer to each data collection instrument that will be submitted with the GenIC as Appendices with sequential number (e.g., Appendix 1), and indicate if the instrument will be modified in the field.
7. Complete the “Burden Estimate” form.
8. Submit the GenIC for review and clearance. Your GenIC must be reviewed and cleared by your:
 - o Center or Division Associate Director for Science
 - o Center or Division PRA Contact (for a list of contacts, see http://intranet.cdc.gov/od/oads/osi/icro/docs/PRA/CIO_PRA_Contact_List.pdf).

Note:

 - o *We recommend sending a draft of your GenIC to the ICRL for pre-clearance review prior to submitting for Division-level clearance.*
 - o *Care should be taken about use of the word **confidential** in the absence of a legal basis on any forms or instruments. Use the term confidential [only] when a data collection has been granted a Certificate of Confidentiality (section 301[d] or an Assurance of Confidentiality (section 308[d]) under the PHS Act. (Page 12-13 October 2012 Procedures)*
9. Email the following to the ICRL:
 - o Completed “Request for Approval Under the Generic Clearance of Emergency Epidemic Investigation Data Collections” GenIC form.
 - o Data collection instruments to be used or modified for the investigation. Each data collection instrument submitted should include the required OMB number and PRA burden paragraph on the cover or first page. At least 1 data collection instrument must be included with the GenIC request. Draft instruments or instruments from previous similar investigations are acceptable.
 - o Completed “Burden Estimate” form.
 - o Letter of invitation from the local, state, or international health authority. The letter should include the following information: 1) background on the outbreak or event; 2) steps already taken toward prevention and control, if any; 3) request for CDC assistance, including objectives of the investigation; and 4) how data will be used to inform prevention and control measures. Sensitive information in the Letter of Invitation not appropriate for public dissemination should be redacted.
 - o The research determination letter (if the investigation is determined to be research) and evidence of IRB approval, if applicable.
 - o Documentation of Center or Division ADS and PRA clearance approval (an e-mail indicating approval is sufficient).

If the request is sent outside business hours and immediate approval is needed, notify the ICRL by phone that the request has been submitted. Hard copies of original, signed documents should be sent via inter-office mail to the ICRL at MS E-92.

10. 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 for an EEI GenIC, the ICRL will submit the request to the CDC Information Collection Review Office for OMB approval.
11. CDC staff may deploy and begin planning the investigation once the request is submitted to OMB.
12. Data collection cannot begin until OMB has approved the information collection or until 72 hours after OMB is notified of the investigation (after which time approval is assumed).
13. The investigation primary contact or designee must be available to respond to questions about the investigation during OMB's 72-hour review period.
14. Upon receiving OMB approval, the ICRL will notify the program and data collection may proceed for up to 90 days.
15. The cover or first page of *each* data collection instrument **must** include the OMB number and expiration date (0920-1011; expires 03/31/2017) 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.
 - o See example "Data Collection Instrument Cover Page" for placement and language.
16. 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. **Note: Refrain from using the word *confidential*.**
17. Within 5 business days of the completion of data collection, submit to the ICRL via e-mail a final copy of all data collection instrument(s) and the completed "Burden Memo."

Questions or Comments?

Contact Danice Eaton, the EEI Information Collection Request Liaison (ICRL).

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MS E-92

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