Attachment F. Steps for Conducting a CSOI

Step-by-Step How to Use the Generic Clearance for Emergency Cruise Ship Outbreak Investigations (CSOIs) Data Collections

To conduct a CSOI with more than 9 non-Federal participants, follow these steps:

1. Review the CSOI Generic Clearance OMB Package (OMB No. 0920-1255).
2. If you have questions about whether your proposed investigation meets the criteria for a CSOI, please contact the CSOI Information Collection Request Liaison (ICRL).
3. If a 24-hour emergency approval will be requested, notify by telephone and then send the advance notification email, "GenIC Expedited Approval Request Notification," to the CSOI ICRL. This email will give ICRO, HHS, and OMB advance notification that an expedited request for an Emergency Cruise Ship Outbreak Investigation (CSOI) will be received with justification.
4. Complete the "Request for Approval Under the Generic Clearance of Emergency Cruise Ship Outbreak Investigations Data Collections" form (Attachment H).
5. Submit the following to the ICRL in STARS:
   - Completed "Request for Approval Under the Generic Clearance for Emergency Cruise Ship Outbreak Investigations" form (Attachment H)
   - The research determination form will be generated for each CSOI in STARS.
6. The ICRL will review the request and determine whether it meets the criteria for the CSOI Generic Clearance in STARS. If the request meets the criteria, the ICRL will submit the request to the CDC Information Collection Review Office for OMB approval by email.
7. CDC staff may deploy and begin planning the investigation once the request is submitted to OMB.
8. Data collection cannot begin until OMB has approved the information collection or until 24 hours after OMB was notified of the investigation.
9. The investigation lead or designee must be available to respond to questions about the investigation during OMB's 24-hour review period.
10. Upon receiving OMB approval, ICRL will notify the program and data collection may proceed for up to 30 days.
11. On the cover or first page of <u>each</u> data collection instrument, include the OMB number and expiration date (0920-1255; expiration date 03/31/2022 -to be updated as needed) 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.
12. 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.
13. Within 7 business days of the completion of data collection, submit to the ICRL a final copy of all data collection instrument(s) and the completed "Burden Memo" via STARS as a PRA change request. The ICRL will email the change request package to ICRO for processing and OMB approval.