Emerging Infections Program (EIP)
Non-substantive Change Request
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<u>Background</u>
The National Center for National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) of the Centers for Disease Control and Prevention (CDC) is requesting approval of a non-substantive change to the approved package under OMB no. 0920-0978; expiration date 8/31/2016.

These forms are used to conduct surveillance to determine the incidence and epidemiologic characteristics of invasive disease due to *Haemophilus influenzae*, *Neisseria meningitidis*, group A *Streptococcus*, group B *Streptococcus*, and *Streptococcus pneumoniae.*, specific foodborne diseases that is captured within FoodNet, Influenza (specifically for the All Age Influenza Hospitalization Surveillance (Flu Hosp) project), and Healthcare Associated Infections-Community Interface (HAIC).

The forms for which approval for changes and additions are being sought include:

1. 2015 ABCs Case Report Form — (Attachment 1)
2. 2015 ABCs Neonatal Infection Expanded Tracking Form — (Attachment 2)
3. 2014 ABCs Non Bacteremic Pneumococcal Disease— (Attachment 3)
4. 2015 FoodNet Variable list — (Attachment 4)
5. 2014-2015 FluSurv-NET Influenza Surveillance Project Case Report Form — (Attachment 5)
6. 2014-2015 FluSurv-NET Influenza Surveillance Project Vaccination History Telephone Survey — (Attachment 6)
7. 2014-2015 FluSurv-NET Influenza Surveillance Project Vaccination History Telephone Survey (Spanish) — (Attachment 7)
8. 2014-2015 FluSurv-NET Influenza Surveillance Project Consent Form — (Attachment 8)
9. 2014-2015 FluSurv-NET Influenza Surveillance Project Consent Form (Spanish) — (Attachment 9)
10. 2015 HAIC-A – CDI Case Report Form (Attachment 10)
11. 2015 HAIC-A – CDI Treatment Form (Attachment 11)
12. HAIC-A – Adult Verbal Consent/Assent (16-17)/Parental Permission, CDI Interview (Attachment 12)
13. HAIC-A – Child Assent (13-15), CDI Interview (Attachment 13)
14. HAIC-A – Screening Questions for CDI Telephone Interview (Attachment 14)
15. HAIC-A – CDI Telephone Interview (Attachment 15)
16. 2015 HAIC-A –Resistant Gram-negative Bacilli Case Report Form (Attachment 16)

The current Estimated Annualized Burden Hours is 12,319 hours based on the 2014 non-substantive change request and this request is proposing a non-substantive change for a total of 22,754 hours (ABCs proposes a change of 135 burden hours, HAIC is new and proposes an addition of 10,300 burden hours, and both FoodNet and FluSurv-NET Influenza Surveillance do not expect a change in burden hours). The following will detail the changes to the EIP surveillance tools including change estimates in burden hours (Table A.1), description of changes and crosswalk of changes.

Change Estimates of Annualized Burden Hours from 2014 to 2015

Table A.1 Estimated Annualized Burden Hours
(Highlighted forms below indicate a change in burden hours in 2015)

Type of Respondent	Form Name	No. of respondents	No. of responses per respondent	Avg. burden per response (in hours)	2014 Total burden (in hours)	2015 Total burden (in hours)
State Health Department	ABCs Case Report Form	10	809	20/60	2697	2697
	Invasive Methicillin-resistant *Staphylococcus aureus* ABCs Case Report Form	10	609	20/60	2030	2030
	ABCs Invasive Pneumococcal Disease in Children Case Report Form	10	22	10/60	68	36
	ABCs Non-Bacteremic Pneumococcal Disease Case Report Form	10	100	10/60	0 (new form)	167
	Neonatal Infection Expanded Tracking Form	10	37	20/60	123	123
	ABCs Legionellosis Case Report Form	10	100	20/60	333	333
	Campylobacter	10	637	20/60	2123	2123
	Cryptosporidium	10	130	10/60	217	217
	Cyclospora	10	3	10/60	5	5
	Listeria monocytogenes	10	13	20/60	43	43
	Salmonella	10	827	20/60	2757	2757
	Shiga toxin producing E. coli	10	90	20/60	300	300
	Shigella	10	178	10/60	297	297
	Vibrio	10	20	10/60	33	33
	Yersinia	10	16	10/60	27	27
	Hemolytic Uremic Syndrome	10	10	1	100	100
	Influenza Hospitalization Surveillance Project Case Report Form	10	400	15/60	1000	1000
	Influenza Hospitalization Surveillance Project Vaccination Telephone Survey	10	100	5/60	83	83
	Influenza Hospitalization Surveillance Project Vaccination Telephone Survey Consent Form	10	100	5/60	83	83
EIP site	CDI Case Report Form	10	1650	20/60	0 (new form)	5500
	CDI Treatment Form	10	1650	10/60	0 (new form)	2750

	Resistant Gram-Negative Bacilli Case Report Form	10	500	20/60	0 (new form)	1667
Person in the community infected with *C. difficile* (CDI Cases)	Screening Form	600	1	5/60	0 (new form)	50
	Telephone interview	500	1	40/60	0 (new form)	333
Total					12,319	22,754

Active Bacterial Core surveillance (ABCs) - Active population-based laboratory surveillance for invasive bacterial diseases

Detailed Description of Changes

A. 2015 ABCs Case Report Form changes include:
   1. Question 32, Receipt of pneumococcal vaccine
      - Directions below checkboxes will be changed to 'If between ≥ 3 months and <5 years of age and an isolate is available for serotyping, please complete the Invasive Pneumococcal Disease in Children expanded form'

B. 2015 ABCs Invasive Pneumococcal Disease in Children Case Report Form changes include:
   1. Removed capture of manufacturer and vaccine name for Diptheria/Tetanus/Pertussis (DTP or DTaP)
   2. Removed capture of manufacturer and vaccine name for Haemophilis influenza type B (Hib)
   3. Removed rows capturing influenza immunizations
   4. Added section on data sources for vaccination history, including
      - What information source was used to identify the health provider
      - How many health providers were contacted
      - What information sources were used to obtain vaccination history

C. 2015 ABCs Non-Bacteremic Case Report Form (new form)

Cross walk of 2015 form changes

A. 2015 ABCs Case Report Form

2014 form	**2015 form**
32. Did the patient receive pneumococcal vaccination?	32. Did the patient receive pneumococcal vaccination?

1 □ Yes 2 □ No 9 □ Unknown If YES, please not which pneumococcal vaccine was received (Check all that apply) 1 □ Prevnar®, 7-valent Pneumococcal Conjugate Vaccine (PCV7) 1 □ Prevnar-13®, 13-valent Pneumococcal Conjugate Vaccine (PCV13) 1 □ Pneumovax®, 23-valent Pneumococcal Polysaccharide Vaccine (PPV23) 1 □ Vaccine type not specified If between ≥3 months and <18 years of age and an isolate is available for serotyping, please complete the Invasive Pneumococcal Disease in Children expanded form.	1 □ Yes 2 □ No 9 □ Unknown If YES, please not which pneumococcal vaccine was received (Check all that apply) 1 □ Prevnar®, 7-valent Pneumococcal Conjugate Vaccine (PCV7) 1 □ Prevnar-13®, 13-valent Pneumococcal Conjugate Vaccine (PCV13) 1 □ Pneumovax®, 23-valent Pneumococcal Polysaccharide Vaccine (PPV23) 1 □ Vaccine type not specified If between ≥ 2 months and <5 years of age and an isolate is available for serotyping, please complete the Invasive Pneumococcal Disease in Children expanded form.

B. 2015 ABCs Invasive Pneumococcal Disease Case Report Form

2014 form	**2015 form**
Title: Active Bacterial Core Surveillance (ABCs) Invasive Pneumococcal Disease in Children	Title: Active Bacterial Core Surveillance (ABCs) Invasive Pneumococcal Disease in Children (aged ≥2 months to <5 years)
Indicate manufacturer for Diptheria/Tetanus/Pertussis (DTP or DTap)	Removed
Indicate vaccine name for Diptheria/Tetanus/Pertussis (DTP or DTap)	Removed
Indicate manufacturer for Haemophilus influenzae type B (Hib)	Removed
Indicate vaccine name for Haemophilus influenzae type B (Hib)	Removed
Indicate dates of immunization for influenza vaccine	Removed
Indicate manufacturer for influenza vaccine	Removed

<table>
<tr><td>Indicate vaccine name for influenza vaccine</td><td>Removed</td></tr>
<tr><td></td><td>Was health care provider information available from the following sources?

Medical chart:
☐ Yes
☐ No
☐ Did not check

Vaccine Registry:
☐ Yes
☐ No
☐ Did not check

Parent/Guardian:
☐ Yes
☐ No
☐ Did not check</td></tr>
<tr><td></td><td>If yes to any sources, how many providers were contacted?</td></tr>
<tr><td></td><td>What sources were used for vaccination history?

Medical chart:
☐ Yes
☐ No
☐ Did not check

Vaccine Registry:
☐ Yes
☐ No
☐ Did not check

Primary Care Provider:
☐ Yes
☐ No
☐ Did not check

Other Provider:
☐ Yes
☐ No
☐ Did not check</td></tr>
</table>

Foodborne Diseases Active Surveillance Network (FoodNet)

Minor revisions have been made to the FoodNet surveillance tool since the last change approval in 2014; however the changes did not result in a change to estimated burden hours for those forms.

Detailed Description of Changes

- Expanded the list of responses for 'AgClinicTestType' to reflect new tests that are now being used in clinical labs.
- Added two new variables related to culture-independent testing for STEC:
  - DXO157
  - DXO157TestType
- Added the following new variables to capture case exposure information to be used for attribution estimates. These variables were developed by a working group consisting of CDC and state health department sites over a two-year period. Variables were pilot-tested in 4 sites for a three-month period for *Salmonella* and *Campylobacter* cases.
  - Meat and poultry
    - CEA_Beef
    - CEA_Beef_grnd
    - CEA_Beef_out
    - CEA_Beef_unckgrnd
    - CEA_Chicken
    - CEA_Chx_grnd
    - CEA_Chx_out
    - CEA_Pork
    - CEA_Turkey
    - CEA_Turkey_grnd
    - CEA_Turkey_out
  - Fish and seafood
    - CEA_Fish
    - CEA_Fish_unck
    - CEA_Seafd
    - CEA_Seafd_unck
  - Dairy
    - CEA_Dairy
    - CEA_Milk_raw
    - CEA_Odairy_raw
    - CEA_Softcheese
    - CEA_Softcheese_raw
  - Eggs
    - CEA_Eggs
    - CEA_Eggs_out
    - CEA_Eggs_unck
  - Fruits and vegetables
    - CEA_Berries
    - CEA_Cantaloupe
    - CEA_Herbs
    - CEA_Lettuce
    - CEA_Spinach
    - CEA_Sprouts
    - CEA_Raw_cider
    - CEA_Tomatoes
    - CEA_Watermelon
  - Water
    - CEA_Ountreat_water
    - CEA_Sewer_water
    - CEA_Swim_treat
    - CEA_Swim_untreat
    - CEA_Well_water
  - Person-to-person
    - CEA_Sick_contact
  - Environmental
    - CEA_Bird
    - CEA_Cat
    - CEA_Dog
    - CEA_Farm_ranch
    - CEA_Live_poultry
    - CEA_Pig
    - CEA_Pocketpet
    - CEA_Reptile_amphib
    - CEA_Ruminants
    - CEA_Sick_pet

Influenza - All Age Influenza Hospitalization Surveillance Project

Minor revisions have been made to the FluSurv-NET Influenza Surveillance tool since the last change approval in 2014; however the changes did not result in a change to estimated burden hours for those forms.

Detailed Description of Changes

A. 2014-15 FluSurv-NET Influenza Surveillance Project_Case Report Form

- A question was added to capture the type of address provided for the patient.
- Additional questions were added to capture additional patient provider contact information.
- To better capture information on where the patient resided at the time of, additional residence type options for question C13 were added.
- Questions regarding Influenza testing results were updated to include new influenza testing types and corresponding result options.
- To better capture information regarding signs/symptoms at the time of admission, question E2 was rephrased to list signs/symptoms as they appear in medical chart – but original intent of question was preserved.
- The options for specifying location of consolidation was removed from questionnaire.
- The section on vaccination status has now an option to record type of vaccination (injected or nasal spray) for children <9 years of age.

B. 2014-2015 FluSurv-NET Influenza Surveillance Project_Vaccination History Telephone Survey (Changes Account for the English and Spanish Version)

- Addition of a question to capture the type of vaccination (injected or nasal spray) received by patients <9 years of age.

C. 2014-2015 FluSurv-NET Influenza Surveillance Project_Consent Form (Changes Account for the English and Spanish Version)

- Location of reference material for continuation of interview was updated to reflect current location.

Cross walk of 2015 form changes

A. 2014-15 FluSurv-NET Influenza Surveillance Project_Case Report Form

Question on 2013-14 Form	Question on 2014-15 Form
N/A	**A10. Address Type: ___________**
N/A	**A16. Primary Provider (PCP) Name 2: ______________**
N/A	**A17. Primary Provider (PCP) Phone 2: ______________**
N/A	**A18. Primary Provider (PCP) Fax2: ______________**
E13. Where did patient reside at the time of hospitalization? ☐ Private residence ☐ Rehabilitation facility ☐ Group home/Retirement home ☐ Assisted living/Residential care ☐ Homeless/Shelter	**E13. Where did patient reside at the time of hospitalization?** ☐ Private residence ☐ Alcohol/Drug Abuse Treatment ☐ Group home/Retirement home ☐ Homeless/Shelter ☐ Hospitalized at birth

☐ Nursing home ☐ Unknown ☐ Other, specify: ______________________	☐ Jail/Prison ☐ LTACH/Transitional Care (TCU) ☐ Mental Hospital ☐ Nursing home ☐ Rehabilitation facility ☐ Hospice ☐ Unknown ☐ Other, specify: ____________________
D1-4. Test 1-4: ☐ Rapid ☐ RT-PCR ☐ Viral Culture ☐ Serology ☐ Fluorescent Antibody ☐ Method Unknown/Note Only	**D1-4. Test 1-4:** ☐ Rapid ☐ Molecular Assay ☐ Viral Culture ☐ Serology ☐ Fluorescent Antibody ☐ Method Unknown/Note Only
D1a-4a. Result: ☐ Flu A (not subtyped) ☐ Flu B ☐ Flu A & B ☐ Flu A/B (Not Distinguished) ☐ 2009 H1N1 ☐ H1, Seasonal ☐ H1, Unspecified ☐ H3 ☐ Flu A, Unsubtypable ☐ Negative ☐ Unknown ☐ Other, specify: ___________________________	**D1a-4a. Result:** ☐ Flu A (no subtype) ☐ Flu B(no genotype) ☐ Flu A & B ☐ Flu A/B (Not Distinguished) ☐ 2009 H1N1 ☐ H1, Unspecified ☐ H3 ☐ Flu A, Unsubtypable ☐ Flu B, Yamagata ☐ Flu B, Victoria ☐ Negative ☐ Unknown Type ☐ Other, specify: ___________________________
E2. Acute conditions at admission (Check all that apply): ☐ Acute respiratory illness ☐ Asthma and/or COPD exacerbation ☐ Fever ☐ Pneumonia ☐ Other respiratory or cardiac conditions ☐ Other, neither respiratory nor cardiac conditions ☐ Unknown	**E2. Acute signs/symptoms at admission *[within 2 weeks prior to positive flu test]:*** ☐ Altered mental status/confusion ☐ Chest pain ☐ Congested/runny nose ☐ Conjunctivitis/pink eye ☐ Cough ☐ Diarrhea ☐ Fever/chills ☐ Headache ☐ Myalgia/muscle aches ☐ Nausea/vomiting ☐ Rash ☐ Seizures ☐ Shortness of breath/resp distress ☐ Sore throat ☐ Wheezing ☐ Other, non-respiratory
E3. Date of onset of acute respiratory symptoms: ____/ ____/ ____ ☐ Unknown	**E3. Date of onset of acute respiratory symptoms *[within 2 weeks prior to positive flu test]*:** ____/ ____/ ____ ☐ Unknown
E3a. If no respiratory symptoms, date of onset of acute illness resulting in hospitalization: ____/ ____/ ____ ☐ Unknown	**E4. Date of onset of acute condition resulting in current hospitalization:** ____/ ____/ ____ ☐ Unknown
E9i. Immunocompromised Condition ☐ Yes ☐ No/Unknown ☐ AIDS or CD4 count < 200 ☐ Cancer diagnosis in last 12 months ☐ Complement deficiency ☐ HIV Infection ☐ Immunoglobulin deficiency ☐ Immunosuppressive therapy ☐ Organ transplant	**E10i. Immunocompromised Condition** ☐ Yes ☐ No/Unknown ☐ AIDS or CD4 count < 200 ☐ Cancer: current/in treatment or diagnosed in last 12 months ☐ Complement deficiency ☐ HIV Infection ☐ Immunoglobulin deficiency ☐ Immunosuppressive therapy ☐ Organ transplant

☐ Stem cell transplant (e.g., bone marrow transplant) ☐ Steroid therapy (taken within 2 weeks of admission) ☐ Other, specify__________________	☐ Stem cell transplant (e.g., bone marrow transplant) ☐ Steroid therapy (taken within 2 weeks of admission) ☐ Other, specify__________________
E9k. Other ☐ Yes ☐ No/Unknown ☐ Liver disease (e.g., cirrhosis, chronic hepatitis, hepatitis C) ☐ Morbidly obese (ADULTS ONLY) ☐ Obese ☐ Pregnant ☐ If pregnant, specify gestational age in weeks: ________ ☐ Unknown gestational age ☐ Post-partum (two weeks or less) ☐ Other, specify _______________	**E10k. Other** ☐ Yes ☐ No/Unknown ☐ Intravenous drug use ☐ Liver disease (e.g., cirrhosis, chronic hepatitis, hepatitis C) ☐ Systemic lupus erythematosus/SLE/Lupus ☐ Morbidly obese (ADULTS ONLY) ☐ Obese ☐ Pregnant ☐ If pregnant, specify gestational age in weeks: ________ ☐ Unknown gestational age ☐ Post-partum (two weeks or less) ☐ Other, specify _______________
H1f. Human metapneumovirus ☐ Yes, positive ☐ Yes, negative ☐ Not tested/Unknown **Date**: ____/____/____	**H1f. Parainfluenza 4** ☐ Yes, positive ☐ Yes, negative ☐ Not tested/Unknown **Date**: ____/____/____
H1g. Rhinovirus ☐ Yes, positive ☐ Yes, negative ☐ Not tested/Unknown **Date**: ____/____/____	**H1g. Human metapneumovirus** ☐ Yes, positive ☐ Yes, negative ☐ Not tested/Unknown **Date**: ____/____/____
H1h. Other, specify: ______________ ☐ Yes, positive ☐ Yes, negative ☐ Not tested/Unknown **Date**: ____/____/____	**H1h. Rhinovirus/Enterovirus** ☐ Yes, positive ☐ Yes, negative ☐ Not tested/Unknown **Date**: ____/____/____
N/A	**H1i.Coronavirus (type):____________** ☐ Yes, positive ☐ Yes, negative ☐ Not tested/Unknown **Date**: ____/____/____
J2c. Please specify location for bronchopneumonia/pneumonia/consolidation/lobar infiltrate/air space density/opacity: ☐ Single lobar ☐ Multiple lobar (unilateral) ☐ Multiple lobar (bilateral) ☐ Unknown	**Removed**
K2a. If discharged alive, please indicate to where: ☐ Home ☐ Other hospital ☐ Hospice/Home hospice ☐ Homeless/Shelter ☐ Rehabilitation Facility ☐ Group home/Retirement home ☐ Assisted living/Residential Care ☐ Home with Services ☐ Nursing home ☐ Unknown ☐ Other, specify: _____________________	**K2a. If discharged alive, please indicate to where:** ☐ Private residence ☐ Alcohol/Drug Abuse Treatment ☐ Assisted living/Residential Care ☐ Group home/Retirement home ☐ Home with Services ☐ Homeless/Shelter ☐ Jail/Prison ☐ LTACH/Transitional Care (TCU) ☐ Mental Hospital ☐ Nursing home ☐ Rehabilitation Facility ☐ Hospice ☐ Unknown ☐ Other, specify: ________________
M1. Did patient receive the influenza vaccine for the current influenza season? ☐ Yes ☐ No ☐ Unknown	**Removed**

M2-M6. [*vaccination history source]*	**M1-M4. [*vaccination history source]***
☐ Yes ☐ Yes, specific date unknown ☐ No ☐ Unknown ☐ Not Checked	☐ Yes, full date known ☐ Yes, specific date unknown ☐ No ☐ Unknown ☐ Not Checked
N/A	**M1b-M4b. If patient < 9 yrs, specify vaccine type:** Injected Vaccine Nasal Spray/FluMist Combination of both Unknown type

B. 2014-2015 FluSurv-NET Influenza Surveillance Project_Vaccination History Telephone Survey

Question on 2013-14 Survey	Question on 2014-15 Survey
N/A	1b) What type of flu vaccine did [you / child's name] receive? ☐Injected Vaccine ☐Nasal Spray/FluMist ☐Combination of both ☐Unknown type

C. 2014-2015 FluSurv-NET Influenza Surveillance Project_Consent Form

Question on 2013-14 Consent Form	Question on 2014-15 Consent Form
Hello. My name is __________ from the _____[state] Department of Public Health. May I speak to ______ [patient's name /parent of [child's name]] . We are working with the Centers for Disease Control and Prevention and other health departments to learn more about influenza disease or the flu. To do this, we are talking to people who have been in the hospital with the flu. We want to look at things that may affect their illness and whether they were vaccinated against the flu. Because you/your child [or NAME if speaking with proxy] were in the hospital for the flu beginning on _______[day admitted], I would like to ask you a few questions about whether you/your child [or NAME if speaking with proxy] received the flu vaccine this season. This will take about five minutes. Your participation is voluntary and if you choose to refuse it will not affect any medical care or benefits you receive. All of your responses will be kept confidential as much as the law allows. You may refuse to answer any questions and may stop at any time. This information will help [State/Local Health Department] and CDC better describe influenza-associated hospitalizations. Additionally, this information may help us improve vaccination recommendations for flu and better protect the public's health. There is no other benefit to you for answering these questions. There is also no risk to you. If you have any questions about the study, you may call _____[state contact] at the Department of Public Health at XXX-XXX-XXXX. Do you have any questions before I begin? May I continue with this interview? ☐ Yes ☐ No If YES, go to Appendix F. If NO: Thank you for your time. Have a good day	Hello. My name is __________ from the _____[state] Department of Public Health. May I speak to ______ [patient's name /parent of [child's name]] . We are working with the Centers for Disease Control and Prevention and other health departments to learn more about influenza disease or the flu. To do this, we are talking to people who have been in the hospital with the flu. We want to look at things that may affect their illness and whether they were vaccinated against the flu. Because you/your child [or NAME if speaking with proxy] were in the hospital for the flu beginning on _______[day admitted], I would like to ask you a few questions about whether you/your child [or NAME if speaking with proxy] received the flu vaccine this season. This will take about five minutes. Your participation is voluntary and if you choose to refuse it will not affect any medical care or benefits you receive. All of your responses will be kept confidential as much as the law allows. You may refuse to answer any questions and may stop at any time. This information will help [State/Local Health Department] and CDC better describe influenza-associated hospitalizations. Additionally, this information may help us improve vaccination recommendations for flu and better protect the public's health. There is no other benefit to you for answering these questions. There is also no risk to you. If you have any questions about the study, you may call _____[state contact] at the Department of Public Health at XXX-XXX-XXXX. Do you have any questions before I begin? May I continue with this interview? ☐ Yes ☐ No If YES, go to Appendix 7. If NO: Thank you for your time. Have a good day.

<u>Healthcare Associated Infections-Community Interface (HAIC)</u>:

The Healthcare-Associated Infections/Community Interface Activity (HAIC-A) is the newest of the EIP's major activities, and was launched in 2009 with support from American Recovery and Reinvestment Act funds. The HAIC-A is now a collaboration between CDC and the 10 state health departments and academic partners of the EIP network, in California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee. Healthcare-associated infections (HAIs) are major threats to patient safety and public health in the United States. Elimination of HAIs is a priority of the Department of Health and Human Services and a CDC Winnable Battle. The HAIC-A contributes to the goal of eliminating HAIs through its mission to promote patient safety and healthcare quality by critically evaluating the epidemiology and public health impact of HAIs to understand emerging pathogens and populations-at-risk and to inform prevention interventions. The HAIC-A conducts population-based surveillance for urgent threats to patient safety, including *Clostridium difficile* infection (CDI) and antibiotic-resistant Gram-negative bacilli. This change request seeks to bring these HAIC-A population-based surveillance projects under the EIP OMB clearance order. As with ABCs surveillance described above, upon verification of a positive laboratory result and confirmation of residence within the pre-defined EIP catchment area, each EIP site conducts data abstraction of the medical chart and laboratory report to complete the standardized case report forms. HAIC data collection forms (Attachments 10, 11, 16) are used by sites to review medical records and collect demographic and clinical information on laboratory-confirmed cases of *Clostridium difficile* infection (CDI) and resistant Gram-negative bacilli. Additional information for putative community-associated CDI cases is collected through patient interview (Attachments 12-15).

Each participating EIP site will destroy identifiers at the earliest opportunity, unless there is a public health or research justification for retaining the identifiers or they are required to by law.

Information in Identifiable Form (IIF) will be collected by each EIP site, and de-identified prior to its transmission to CDC. Other information that may be collected could include hospitalization history, lab test results and culture information, symptoms, discharge diagnosis, Antiviral treatments, ICD 9 codes, healthcare worker status, Influenza vaccination status, and underlying medical conditions. Information transmission occurs via a secure CDC website. The case report form does not involve web-based data collection methods, although case report form data are entered into a CDC-developed, approved web-based data management system for some activities, and does not refer respondents to websites.

HAIC-A CDI and resistant Gram-negative bacilli data are collected by EIP site personnel on paper case report forms (Attachments 10, 11, 15, 16). Case tracking information is entered into locally-housed case tracking systems; identifiable data entered into these secure, local systems are not shared with CDC. Case information (without identifiers, save for date of birth) from these local systems is then imported or transmitted via a secure web service into CDC-developed, approved, web-based data management systems.