Pilot initiative to assess the feasibility of expanding ILINet surveillance activities to incorporate population-based rates of influenza

APPLICATION

Issuing Organization

Council of State and Territorial Epidemiologists (CSTE) at www.cste.org/

Participating Organizations

Centers for Disease Control and Prevention (CDC), at http://www.cdc.gov

Components of Participating Organizations

Influenza Division, National Center for Immunization and Respiratory Diseases (NCIRD/CDC), at http://www.cdc.gov/ncidod/

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Part I – Overview Information

1. Overview

The Council of State and Territorial Epidemiologists and the CDC Influenza Division support the enhancement of influenza surveillance at state and local health departments by promoting initiatives to maximize the utilization of existing surveillance systems for influenza and leverage available resources to inform influenza disease burden estimation. State and local health departments with established epidemiologic and laboratory surveillance systems and reporting informatics will be supported to collaborate with CDC Influenza Division partners to accomplish these goals.

CSTE seeks proposals that will engage local healthcare providers and public health department epidemiologic and laboratory units to create a linkage between virologic and U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) programs. The pilot initiative described will expand activities for a small number of ILINet providers to estimate a population denominator and submit specimens from a subset of ILI patients each week to develop the capacity to determine the influenza attributable proportion of ILI and an extrapolated incidence of influenza-associated ILI. Collection of patient influenza vaccination status will be emphasized, with confirmation of vaccination preferred.

Part II Full Text of Announcement

Section I. Application Description

1. Background

Tracking the incidence of influenza allows for disease burden comparisons across circulating influenza viruses, seasonal epidemics and geographic regions, alerts public health officials of increases beyond usual seasonal activity and improves interpretation of non-specific, syndromic measures of disease. However, the outpatient setting poses many challenges for estimating influenza disease burden, most importantly the difficulty in defining the population under surveillance and the non-specific nature of commonly used case definitions. The influenza-like illness (ILI) case definition is commonly used for influenza surveillance due to the high positive predictive value during periods of influenza virus circulation, although influenza illness is often clinically indistinguishable from illness due to other respiratory pathogens. Therefore, laboratory confirmation of influenza infection is necessary to determine the influenza attributable proportion of ILI during each week of the season.

Currently, the CDC Influenza Division collaborates with state, local, and territorial health departments to conduct surveillance for ILI and influenza year-round in the United States. Through ILINet, outpatient healthcare providers monitor the weekly percent of outpatient visits due to ILI and report directly to CDC. Public health laboratories (PHL), including all state PHLs, play a vital role in virologic surveillance for influenza as part of the U.S. World Health Organization (WHO) Collaborating Laboratories System. Specimen test results from most state public health laboratories are automatically reported to CDC through the Public Health Laboratory Interoperability Project (PHLIP). While these two national surveillance systems are not directly linked, the reporting systems have the capacity to implement a linkage permitting estimation of the proportion of ILI attributable to influenza. This, in combination with estimates ILINet clinics' patient population sizes, could further enable CDC to calculate incidence and inform estimates of influenza burden.

Influenza vaccination status is collected through routine surveillance programs in many countries to estimate vaccine effectiveness (VE). Among outpatients in the United States, VE is estimated through the U.S. Flu-VE Network, a research platform in 5 locations. Incorporation of a linked report of vaccination status for ILI patients tested for influenza and subsequent verification of the vaccination status could enable annual estimation of influenza vaccine effectiveness through routine domestic surveillance and provide complimentary robust calculations to parallel research platforms.

From 2009 through 2017 the Influenza Incidence Surveillance Project (IISP) and expanded Acute Respiratory and Epidemiology Surveillance (ARIES) programs monitored the age-specific incidence of medically-attended ILI and ARI and provided lessons learned about the feasibility and utility of collecting such information in the outpatient setting. Health care providers with a primary care focus and with patient populations of estimated size tracked ILI and ARI patient visits and collected specimens from a subset of patients which were tested for influenza at the state or local health department. These surveillance platforms provided valuable data for CDC, prompting the present initiative to investigate incorporation of these methods into routine surveillance activities.

For the 2017-18 season, CSTE seeks proposals that pilot the expansion of ILINet activities in a small number of ILINet providers to collect specimens from a subset of ILI patients each week according to the ILI case

definition, develop a mechanism to enable the identification of these specimens through PHLIP reports, and utilize methodologies from IISP and ARIES to estimate the attributable proportion of ILI due to influenza and the burden of influenza-associated ILI in the outpatient setting. Funding is open to any state or local health department. Funding awards are dependent on commitment and compliance with core activities, as outlined in the guidance of the current FOA.

2. Objectives

The overarching objective of the partnership activity includes piloting enhancements of existing surveillance systems and informatics to facilitate the exchange of data necessary to determine the weekly proportion of ILI due to influenza and estimate the outpatient disease burden of influenza.

1. Recruit new or existing ILINet healthcare providers to report weekly aggregate counts of ILI and all-cause visit counts by age group to ILINet, collect respiratory specimens from a subset of ILI patients presenting each week, and estimate their patient population size.
2. Collect minimal patient demographic and clinical information and submit specimens to a public health laboratory (PHL) that is currently reporting via PHLIP production (either PHLIP 2.3.1 or PHLIP 2.5.1).
3. Conduct influenza testing of specimens and create a project flag and/or incorporate the ILINet identification number for specimens that are part of this project in the existing PHLIP message.
4. Transmit influenza test results and collected patient information to allow for calculation of the proportion of medically-attended ILI patients with laboratory-confirmed influenza.
5. Collect ILINet provider patient population size (known or estimated) to allow for calculation of the incidence of influenza-associated ILI in the outpatient setting.
6. Collect influenza immunization history through medical chart history or patient self-report and record on the specimen submission form. Report through either PHLIP message or an alternative direct report to CDC, such as via secure file transfer protocol.
7. Confirm vaccination status reports retrospectively through immunization registry and/or medical chart review.

3. Methods

Applicants should propose methods that accomplish the outlined objectives; however, to maximize the comparability of data across awarded sites, some detailed methods are outlined in the following section. Alternatives to the outlined methods are permitted, but should maintain compatible data.

A. Project Period

The funding period is from November 1, 2017 – June 30, 2018. The minimum surveillance period is from December 1, 2017 – June 30, 2018. However, surveillance would ideally begin earlier in October or November, but it is not required.

B. Case definition

Influenza-like illness (ILI) is defined as acute onset fever (temperature of ≥100°F [37.8°C]) with cough and/or a sore throat. *Reported fever qualifies the patient for inclusion.*

C. Surveillance sampling of ILI patients

The pilot initiative aims to have outpatient healthcare providers identify ILI patients and collect specimens each week based on meeting clinical criteria and a sampling algorithm, regardless of rapid test results, suspicion of influenza, patient severity, or other non-systematic prioritization of patients for testing. Applications should outline methods to directly identify patients that meet the ILI case definition and approach them about specimen collection.

D. Provider recruitment and characteristics

Participating state and local health departments ("sites") are responsible for recruiting providers/clinics to participate in this pilot. Recruitment of existing ILINet providers is encouraged to allow for the evaluation of reporting history and compliance.

- Providers must be able to enumerate or estimate the patient population served by the following age groups (years): <5, 5 – 24, 25 – 49, 50 – 64, ≥65. This will serve as an approximation of a population for incidence calculation.
- The combination of all clinics/providers participating must represent all age groups for the jurisdiction.
    - Particular care should be taken to identify providers who serve patients aged ≥50 years, as this is a very difficult population in which to conduct robust surveillance.
- Recruited clinics or providers must allow acute care visits. Providers or clinics that triage acutely ill patients to non-participating clinicians or urgent care clinics, or providers that generally do not see acutely ill patients should not be recruited.
- We encourage provider incentives, even if minimal. While influenza test results will not impact clinical care due to timing, sharing test results with participating providers makes an excellent incentive. Provider agreements or contracts for participation (e.g., memorandum of understanding between health department and provider) are recommended.

E. Patient Population Estimation (aka source population, at-risk population)

Each provider participating in specimen collection must be able to provide an accounting of the number of individual patients under their care by age group. Patient population data may also be collected from non-participating ILINet providers to allow for more robust ILI incidence calculation. Population estimation is only conducted once, ideally at the time the provider is recruited, and may apply to multiple years of data collection if no substantial change in the size or age distribution of the population served has occurred.

Ways to enumerate the patient population include:

- Total number of patients registered with the provider.
- Average number of **unique persons** who have been seen by the provider in a given year (3 years of data desired for making this estimation). This is NOT the same as the number of patient visits each year, since in any given year people may come more than once or they may not have a visit.

F. Weekly Aggregate Data Reporting through ILINet

Aggregate data collection and reporting procedures should be consistent with current ILINet methodologies, with the following requirements:

- For each week, providers should report the number of all ILI and all-cause patient visits (denominator) by the following age groups (years): <5, 5 – 24, 25 – 49, 50 – 64, ≥65.
- Patients with ILI may be identified through direct identification, chief complaints, ICD-10 codes, other electronic sources, or a combination. Proposals should describe the methods used to identify and count ILI patients, including any specific listing of ICD-10 codes or chief complaints. CDC can also provide search terms for chief complaints and ICD codes that have been used previously.
- Reports should be submitted via the ILINet data submission website: https://wwwn.cdc.gov/ilinet/

G. Patient sampling and number of providers

Approximately 100-150 specimens per age group per season (for a total of ≥500-750 specimens per site per season) are needed from each site to calculate a reliable influenza proportion in each site (based on 95% confidence, 7% error, and 15-25% positivity in sample size calculations).

Sites should recruit no fewer than 5 clinics to participate. The number of specimens submitted weekly from each clinic may vary according to clinic size and/or number of clinics participating. We recommend 10 surveillance specimens from a "non-biased" or systematically identified subset of ILI patients per week. Due to seasonal variability and patient refusal, providers may not reach the maximum each week.

- Patient refusal is expected, thus specimen collection should continue until the proposed number of specimens have been collected.
- Based on IISP methodology and best practices, we recommend 5 or more moderately-sized clinics submitting specimens from the first ILI patients to present each week until a maximum of 10 is reached (accounting for patient refusal). Alternatively, a proposal may suggest 10 providers submitting 5 specimens per week, 5 large clinics submitting 5 specimens per week, etc.
- Data from the IISP indicated that small to moderate-sized clinics during an average severity influenza season (e.g., 2010-11, 2012-13) collected between 115 and 669 (median 375) specimens per season, with an average of 116 specimens per provider.
- Theoretically, 5 providers per site x 10 specimens per provider per week x 40 weeks = 2000 possible specimens. ***No IISP site ever experienced or approached this volume of ILI specimens!*** Seasonal variability in ILI resulted in few weeks of the year in which providers have 10 ILI patients willing to have a specimen collected.

H. Patient Data Collection

Only basic demographic data, including at least age, and clinical data, including at least specimen collection date, and specimen type are required to be submitted on sampled patients. The minimum data elements that should be reportable through the PHLIP message.

Additional data elements of interest include date of illness onset, symptoms and/or diagnosis, influenza vaccination status (see Section M), influenza antiviral prescribing, if rapid testing (influenza or other) was

performed and result, and patient race, ethnicity, and gender. We are only requesting data elements already incorporated in the existing LIMS and able to be incorporated into the PHLIP message. Please note, this work should not interrupt routine reporting through PHLIP.

I. Specimen collection

The type of specimen collected is at the discretion of the provider, but must be a respiratory specimen.

- A nasopharyngeal (NP) swab is the optimal upper respiratory tract specimen collection method for influenza testing. However, such specimens cannot be collected from infants and many older patients may not allow an NP specimen to be collected. Alternatively, a combined nasal and throat swab specimen or aspirate specimens can provide good influenza virus yield.
- Single throat swab (oropharyngeal) or nasal swab specimens are permitted, but can have lower influenza virus yield.
- Guidance for influenza specimen collection is available at https://www.cdc.gov/flu/pdf/freeresources/healthcare/flu-specimen-collection-guide.pdf

J. Specimen Storage and Shipping

Specimens should be placed in 3mL tubes with viral transport media (VTM), labelled, and refrigerated at 4 degrees Celsius until received by the state PHL. Instructions for specimen shipping will be in accordance with state or local health department guidelines.

If delivery will be delayed for more than 3-4 days, instructions should include freezing specimens at -70 degrees Celsius (-94 degrees Fahrenheit).

Proposals should include accommodations for shipping of specimens from clinics to the PHL, including frequency during the week.

K. Specimen testing

The state or local public health laboratory (PHL) should process and test specimens.

- Reagents and qualifying ancillary reagents for influenza testing is provided by CDC at no cost to validated PHL through the International Reagent Resource (IRR). Influenza testing should be conducted using the CDC IVD kit including influenza A (subtypes 2009 H1N1, H3) and influenza B (genotypes Yamagata and Victoria).
- Influenza testing results should be reported via PHLIP, including the ILINet ID for submitting provider and the unique patient and/or specimen identifier (caseid or specimen id) used by the laboratory and epidemiology departments, and a project flag that may be needed to identify specimens collected for this surveillance project as needed. The patient/specimen identifiers would be the same as those that are submitted routinely to CDC when specimens are sent for characterization or other reasons.
- For validation purposes, an Excel file containing testing results, the unique patient and/or specimen identifier, and any non-personally identifiable patient data elements collected, but not incorporated into the PHLIP message should be submitted separately to the CDC Influenza

Division. Frequency of reporting the validation file is at the discretion of the site, but should be within 1 month of collection.

- Specimens should be retained by the PHL and accessible for 3 years, unless sent to the CDC Reference Laboratory for further testing or characterization according to CDC specimen submission guidelines.

L. Influenza vaccination status and verification

Collection of influenza vaccination status through routine surveillance is conducted globally, and assessing the feasibility of implementation in US-based surveillance is a priority.

Influenza vaccination status collected prospectively, ideally with verification, or retrospectively is requested.

- Prospective influenza vaccination status may include patient self-report or medical chart collected at the time of clinical visit. Reported vaccination status may be verified using immunization registry and/or medical chart review.
- Retrospective influenza vaccination status may be conducted using immunization registry and/or medical chart review.

Applicants should describe the method that will be used to collect influenza vaccination status, which may be dependent on IRB regulations, data quality and availability. For example, immunization registries are not required in all states thus may vary in quality.

Vaccination status, whether prospective or retrospective, does not need to be incorporated into the PHLIP message and may be reported separately, ideally in the first two weeks of January and again in the first weeks of June.

M. Evaluation

Successful applicants should also demonstrate capacity to participate in a CSTE/CDC-led evaluation at the conclusion of the project period to assess feasibility of implementation of pilot project methods, including successes, challenges, and lessons learned.

Section II. Award Information

1. Mechanism(s) of Support

CSTE will manage all matters related to financial support for this project. CSTE will provide fixed-funding contracts to each of the sites. Funds will be distributed upon contract initiation (25%) and on December 30 (25%), March 30 (25%), and June 30 (25%). In all cases, funds will only be reimbursed upon receipt of invoice from the applicant as well as sufficient progress as determined by CSTE made toward the activities outlined in this FOA and contract agreement with CSTE. Recipients are responsible for allocating appropriate amounts to support activities including compensation for providers and to supplement the PHL for the duration of the project. Contracts will not be automatically renewed yearly.

2. Funds Available

CSTE intends to provide support for up to 10 sites. CSTE will award successful applicants with a maximum of $35,000 per site. Although the financial plans provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the number of applications received.

CSTE receives funding for this project through the Centers for Disease Control and Prevention (CDC) cooperative agreement number: 5U38 OT000143. The development of supplemental surveillance methods is a joint project of CSTE and CDC based on previous CSTE Position Statements. All position statements, including 06-ID-04, are available at www.cste.org. Funds awarded under this announcement are subject to the laws, regulations and policies governing the U.S. Public Health Service grant awards.

Section III. Eligibility Information

1. Eligible Applicants

Applicants should clearly describe their ability to meet the objectives and methods listed in Sections 1.2 and 1.3. State, territorial, large city/county* public health agencies. *A large local public health agency is defined as a city or county health department serving a population of one million residents or greater.

2. Cost Sharing or Matching

Cost sharing, matching, or cost participation is required only for activities that overlap with other CDC funded programs to avoid duplicate funding. For example, if a personnel is fully funded by the Epidemiology and Laboratory Capacity Grant, the same individual cannot receive extra salary through this funding mechanism.

Section IV. Application and Submission Information

1. Content and Form of Application Submission

Applications should include the following headings in the order listed and should address the issues included under each heading. Page limits noted are strongly encouraged, but will not affect the review if it is necessary to exceed.

- Contact information: Principle Investigator (PI) and Surveillance Officer(s) (SO). The PI will serve as the primary contact for this project. Applicants should also indicate who will function as the primary laboratory investigator. Information should include email, mailing address (no PO boxes) and phone number. **1 page limit**
- Surveillance Experience: Applicants should describe their influenza surveillance experience demonstrating the ability to successfully participate in this project and achieve the goals outlined. Details may include participation in IISP, ARIES, or any additional CDC or CSTE surveillance programs or studies that may compliment this platform, such as surveillance in the hospital or community setting. Applications should also include a description of an experienced staff member who will oversee the project's progress. **1 page limit.**
- Methods: Applicants should describe their proposed methods according to those described in the objectives and methods outlined in Sections 1.2 and 1.3. Applications should include at least the following:
    - Describe methods that will be used to identify and recruit health care providers, including the number of providers or clinics planned for recruitment.
    - Describe the methods for determining the patient population.
    - Describe aggregate data that will be collected (compliance with ILINet instructions).
    - Describe the patient specimen collection methods, including sampling strategy and estimated number of specimens to be collected weekly and/or for the season.
    - Describe the patient data reporting and specimens shipping methods.
    - Describe capacity to participate in CDC/CSTE-led evaluation of pilot project.
    - **4 page limit**
- Laboratory test methods: Applicant should describe the influenza testing algorithm, addressing the ability to incorporate a project flag and/or ILINet ID into PHLIP to allow CDC to identify specimens collected for this project. Applicants should also describe the frequency of reporting data directly to CDC for validation. **2 page limit – do not include assay package inserts**
- IRB: Human subject review process for the applicant if necessary. **½ page limit**
- Letters of Support: A letter of support from the participating public health laboratory, and at least three providers or representative organization is required and must address commitment to participate and ability to integrate protocol. **1 page limit per letter**
- Budget: Vague budgets may not be considered. Proposed budget should be reasonable and include the amount of funding needed and how it will be appropriated to coordination personnel time, supplies, laboratory testing, and services such as informatics, information technology support, specimen shipping, and provider/clinic incentives for participation. Do not include the cost of reagents or supplies that are provided by the IRR. **No limit**

For further assistance, technical questions, or inquiries about the application, contact Monica Schroeder at CSTE (770-458-3811 or mschroeder@cste.org). CSTE and CDC will be available to speak to potential applicants to discuss administrative and technical questions. Upon request, all questions and answers will be made available to all potential applicants during the application process.

2. Submission Dates and Times

A completed letter of intent should be sent by email to CSTE:

Monica Schroeder
Program Analyst II
Council of State and Territorial Epidemiologists
2872 Woodcock Blvd., Suite 250
Atlanta, GA 30341
770-458-3811 (phone)
770-458-8516 (fax)
mschroeder@cste.org

Submission, Review and Anticipated Start Dates
Letter of Intent Receipt Date: September 15, 2017 (required)
Application Submission Receipt Date: October 20, 2017
Award notification date: November 3, 2017
*subject to change based on the availability of funding
Award Disbursement Date: After November 3, 2017
Budget Period: November 1, 2017 – June 30, 2018

Submitting an Application
An electronic copy of the completed application should be submitted electronically to mschroeder@cste.org by October 20, 2017. All application materials must be submitted in one electronic file attachment. Applications must be received by CSTE no later than 11:59pm Eastern on October 20, 2017. Applications received after this deadline may not be reviewed.

The receipt deadline for all application components is 11:59pm Eastern on October 20, 2017. Submitted appendices should be kept at a minimum and may not be reviewed as part of the application process. Inquires about successful receipt of application by CSTE will be sent only upon request by email to mschroeder@cste.org .

Application Processing
All applications received will be reviewed by November 3, 2017. Applications will be reviewed based on criteria described in Section V.

Section V. Application Review Information

1. Criteria and Prioritization

The scientific merit of the proposed project as determined by the objective review panel will be based on the following criteria and associated weights:

Maximum points

Completeness and appropriateness of the application: 15

- Completeness of applications, such that all content in Sections 1.2, 1.3, 3.1, and 4.1 are addressed.
- The extent to which the budget is clear, reasonable and consistent with the purpose of the announcement and the proposed objectives for the program.
- Letters of support from providers and PHL included.

Ability to comply with data collection methods: 40

- Ability to enroll ≥5 providers who can define their patient population.
- Ability to comply and participate in ILINet surveillance, including the reporting of weekly all-cause (denominator) visits by age group.
- Ability to collect surveillance specimens according to a systematic sampling scheme that identifies ILI patients by case definition at a sufficient volume to make robust calculations of the percent of patients positive for influenza by age group.

Public health laboratory capacity: 30

- Ability of the PHL to perform influenza testing and handle increased volumes of specimens for testing.
- Currently reporting to national surveillance through PHLIP.
- Ability to incorporate a project flag and ILINet ID that permits the automated identification of specimens collected for this surveillance program from participating outpatient clinics, and minimal epidemiologic data as outlined.

Demonstrated success in surveillance activities (previous IISP/ARIES/other surveillance): 15

- Ability to enroll providers/clinics in surveillance with consistent participation, including reporting and/or specimen collection.
- Tested a sufficient number of specimens relative to **IISP/ARIES/other** surveillance goals.
- Ability to engage in timely data collection, specimen testing, and reporting.
- Participation in other CSTE or CDC-led influenza or respiratory disease surveillance programs that could align with this pilot for greater understanding of influenza disease burden in hospital, other outpatient, or community settings.

Grand Total: 100

2. Review and Selection Process

Eligible applications that are complete will be evaluated for scientific and technical merit by CSTE and CDC/Influenza Division in accordance with the review criteria stated within this announcement. Funding awards will be made based upon the quality of the submitted proposal and the ability of the applicant to meet the objectives stated above.

Section VI. Award Administration Information

1. Award Notices

Applicants will be notified via email or phone by November 3, 2017. Award date is subject to change based on the availability of funding and any delays in award notification will be shared with all applicants.

2. Recipient Responsibilities

Each recipient public health department and PHL will have primary responsibility for the following:

- Providing scientific and management oversight for the overall project at participating provider sites, including surveillance design and conduct, data collection and reporting, quality control, and collaborations with other awardees, CDC, and CSTE.
- Obtaining the appropriate human subjects clearances at local sites if required.
- Working with CDC scientists to refine protocols and data collection instruments.
- Providing written progress reports that describe performance milestones and invoices to CSTE as required in the contract agreement.
- Initiate a formal agreement with providers to ensure participation and submission of samples.
- Ensuring that any changes in PHLIP messaging will not interrupt or delay routine reporting for surveillance through PHLIP.
- Agreement to abide by the collaborative guidelines in the Data Use Agreement (Appendix E).

3. CSTE Responsibilities

During the established grant period, CSTE is responsible for:

- Monitoring the terms of the contract agreement between the recipient and CSTE.
- Collecting invoices from the recipient and paying invoices according to the terms of the contract agreement between the recipient and CSTE.
- Providing information about the progress of the program to the CSTE Executive Board and to CDC.
- Reviewing and distributing progress reports and the final report with CDC.
- Providing technical expertise.
- Participate and staff the Planning and Coordination Committee (PCC) meetings
- Fund travel of PCC members to in person meetings and technical consultations. Convene an independent review panel of experts to provide an objective review of the submitted applications.
- Abide by the collaborative guidelines described in the Data Use Agreement.
- Providing CSTE staff to support the day to day activities of thisproject at both CSTE and CDC.

4. CDC/Influenza Division Responsibilities

CDC/Influenza Division will have substantial programmatic involvement as described below:

- If IRB review is deemed necessary at the state/local level, CDC will assist the recipient in the development of a research protocol that will be acceptable for local site IRB review and approval.

- CDC will provide technical advice concerning laboratory methods for the diagnosis of influenza if needed and may perform or suggest quality control testing of the laboratory methods used to diagnosis influenza at each funded site.
- CDC will provide the reporting mechanism and maintain a database for all project related data including ILI and patient visit tallies and the specimen related case report form.
- CDC will work with awarded applicants as needed to determine appropriate methods to define the patient population.
- CDC will provide technical expertise and ensure appropriate training for personnel from health departments.
- Participate on an independent review panel convened by CSTE to provide an objective review of the submitted applications.
- Abide by the collaborative guidelines described in the Data Use Agreement (Appendix E).

5. Collaborative Responsibilities

CSTE and CDC in conjunction with the recipient contacts for all awarded projects will continue participation in a Planning and Coordination Committee (PCC). Each recipient contact will be a member of the PCC and will participate in its activities. A CDC staff member will serve as a member of the PCC and schedule its first meeting. The PCC will function to:

- Establish goals, promote collaboration, share best practices, and coordinate surveillance activities among members of the PCC.
- Provide guidance to investigators regarding project implementation and sustainability for the duration of the influenza season.
- Evaluate monthly progress of all funded project activities
- Meet by phone at least once per month and up two twice per year for an in person meeting. CSTE will provide non-federal travel support if required.
- Members of the PCC may be required to travel to other PCC health agencies up to twice a year to provide or receive technical support. CSTE will provide non-federal travel support if required.

Appendix **Data Sharing Guiding Principles**

1. **Primary Multi-Site Investigations**
    - Primary multi-site investigations are those designed to accomplish the core surveillance objectives as stated in the funding opportunity announcement
    - CDC investigators, as listed in the funding opportunity announcement, will lead the primary multi-site investigations to accomplish the core surveillance objectives. They will work closely with the steering committee to ensure that high quality results are generated and will be responsible for running the project and writing the final publication.

2. **Steering Committee**
    - A steering committee will be comprised of the participating sites, CDC and CSTE. The steering committee is responsible for deciding secondary multi-site and single-site investigations will be pursued.

3. **Process for Selecting Proposed Investigations:**

    a. Submission of Secondary Multi-Site Investigation

    Written proposal should be submitted electronically to the CSTE project officer. The proposed work must not already be a part of core surveillance objectives as stated in the funding opportunity announcement or contained within a proposal for which permission was already granted. Proposals should include the following sections

    1. Title
    2. Investigator(s)
    3. Background
    4. Public health rationale
    5. Primary objective(s)
    6. Methods
    7. Analysis plans
    8. Table Shells
    9. Timeline
    10. References
    11. Proposed journal/publication and other presentations, such as conferences

    b. Review and Approval of Proposals

    Each submitted proposal (including title and the lead author) will be distributed to the members of the steering committee for review. Within one week, the steering committee will discuss the proposal on a conference call or via email. Following the discussion, any concerns will be submitted to the lead author who will then have one week to address them. The steering committee will then vote on the final approval of the proposal. Once approval is granted, communication of project approval will be sent to the lead author. Significant changes in a concept or in the variables to be analyzed will require resubmission of the proposal.

    c. Data and Specimen Requests

    Once a proposed investigation is approved, the lead investigator should communicate with CDC to start collaboration in investigation design, creation of analytical datasets, selection of banked specimens, and data analysis.

    d. Submission of a Single-Site Investigation Proposal

    Written proposals should be submitted electronically to the CSTE project officer. The proposed work must not already be a part of core surveillance objectives as stated in the funding opportunity announcement or contained within a proposal for which permission was already granted. Proposals should be in the form of a descriptive summary including the following:

    1. Statement of intent
    2. Investigators
    3. Methods

4. Timeline
5. Proposed journal/publication and other presentations, such as conferences

4. Publications

e. Review of Abstracts, Presentations, Publications

All abstracts, posters, manuscripts, and presentations resulting from secondary multi-site investigations must be reviewed by the steering committee (including CSTE and CDC) before any presentation to a formal scientific meeting or prior to submission for publication. At least 4 weeks should be anticipated for the steering committee review. The CDC disclaimer needs to be on all publications with CDC authors and acknowledgement of CSTE's agreement of funding.

Abstracts, manuscripts, and presentations resulting from single-site analysis also require steering committee review in order to decide the funding line. If the CDC and CSTE do not agree with the results or conclusions of the publication, it will be necessary to add to the funding line that the conclusions do not represent the position of the CDC or CSTE.

All final abstracts and manuscripts must be reviewed by CDC prior to submission for publication with any CDC co-author.

Presentation or manuscript submissions which do not have prior steering committee approval and CDC clearance may result in a denial of access to data. In addition, presentation or submission of unapproved manuscripts could be subject to withdrawal from committee or journal review.

Publications and presentations shall be in compliance with the rules and procedures of the disclosure set forth in the Privacy Act. Confidential or proprietary information of another party shall not be disclosed without the prior written consent of the individual or institution. Privacy Act compliance and documentation of written disclosure consents are the responsibility of each institution involved in the publication.

f. Credit and Authorship

All publications and presentations should acknowledge that the data were collected through "Influenza Incidence Surveillance Project". All publications and presentations should credit participating institutions, CSTE and the CDC.

Each co-author should follow the uniform requirements published by the International Committee of Medical Journal Editors (ICMJE). Each author should contribute to (1) conception and design, or analysis and interpretation of data; (2) drafting the publication or revising it critically for important intellectual content; and (3) approve the final version of the publication.

On secondary multi-site publications, each site, CSTE and the CDC will determine its co-author(s). Each site, CSTE and the CDC can specify more than one co-author. Each site, CSTE and the CDC may decline authorship on a multi-site publication. If necessary, the steering committee will be the arbiter of the final authors list for a publication. Acknowledgements on a manuscript may include more than one person per site. On single site publications, decision will be made between the site, CSTE and CDC whether there should be at least one CDC and/or CSTE co-author.