Form Approved

OMB Number 0925-XXXX

Exp. Date: XX/XX/XXX

Public reporting burden for this form is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-XXXX). Do not return the completed form to this address.

**CEIRS Human Influenza Surveillance Study Form 14A: 10% Data Accuracy Report**

**Instructions**: This form is to be completed every month during Clinical Study

Site: \_ Date: / /

Person Completing this Form:

Enrollment Dates for This Month Start: / / End: / /

Number of Subjects Enrolled this month: \_

Number of Subjects Required for QA : (10% or a minimum of 4 subjects, whichever is greater)

*For each subject requiring QA, please complete the following table:*

**Instructions**: Complete this chart if QA required and place this form in the corresponding subject’s case report forms binder tab.

Subject ID:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Criteria** | **Number of Corrections** | **Incomplete Y/N** |
| **Eligibility** | Form 2A: All inclusion criteria met and documented properly |  |  |
| **Enrollment** | Form 4A: Demographic and exposure Information captured and documented properly |  |  |
| Form 5A: Current symptoms captured and documented properly |  |  |
| Form 6A: Medical history captured and documented properly |  |  |
| Form 7A: (If applicable) Samples collected, processed, and stored properly |  |  |
| **Follow Up** | Form 8A: Follow Up results documented properly |  |  |
| Form 9A: ED Chart Review captured and documented properly |  |  |
| Form 10A: Inpatient Chart Review captured and documented properly |  |  |
| **Quality Control** | Form 12A: Subject Checklist complete |  |  |