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H1N1 Registry Pediatric

REDCap Instructions

Initiating a Patient in REDCap:

1. Enter website and log in:
2. Select "Patient" from the list of forms on the right of the screen.
3. Place curser in: "**New Patient ID**" field and enter the patient H1N1 subject number.
    a. The subject number will be 6 digits: first digit should always be "9", the second two represent site number the last three digits are the chronologic patient number. **Example: if you are site 09 and you are entering your ninth H1N1 subject, the subject number will be 909009.**
    b. After entering the subject number, hit the "tab" button on your keyboard.
4. Change the status to "complete" and select one of the save options:
    a. "Save" will save the data and returns to the patient selection screen for the current form
    b. "Save and continue" will save the patient into the system and keep the same form open.
    c. "Save and go to next form" will save the patient data and automatically open the next CRF for this subject.

Accessing an existing patient and entering/saving data:

1. From the "Patient" screen, select the patient you want from the "complete" or "incomplete" drop down menus. The list of forms on the right side of the screen will now appear with stop lights to indicate which forms that are complete (green) and incomplete (red) for this patient.
2. Once a patient is selected, clicking on the stop light in front of the form you wish to complete will open the form for that patient. ***NOTE:*** *clicking on the text of the form name rather than the stop light will allow you to complete this form for a different patient.*
3. Once you have completed entering the data, select complete or incomplete to indicate the form status and chose one of the save options from the bottom of the screen.

Study Days Description:

The case report forms will ask for data from "ICU days rather that "study days". ICU admission day refers to the day/date that the patient was admitted to the ICU. This day/date would also be considered "ICU day 1".

Example: If a patient is admitted to the ICU on November 2, 2009 then November 2 would be "ICU admit day". November 4, 2009 would be ICU day 3.

Section 1

Case Definition and ICU Location

Complete form at baseline.

1. Case definition: please choose confirmed or suspected. A ***confirmed case*** of influenza (any strain) virus infection is defined as a person with an acute illness admitted to an ICU with laboratory confirmed influenza A or B virus infection A ***suspected case*** of influenza virus infection is defined as a person admitted to the ICU without a positive influenza test but where the clinical team's suspicion for influenza was enough to treat empirically with anti-virals for influenza for the lesser of 5 days or until death. If another diagnosis is found to explain the patient's acute illness (e.g. RSV or *Legionella pneumophila*)) then the person should NOT be considered a suspected case for this registry.	☐ Confirmed case ☐ Suspected case
2. First 3 digits of patient's zip code:	___ ___ ___
3. Type of ICU: Select the option that indicates the patient's location on day 0 (first ICU day).	☐ MICU or PICU ☐ SICU or Surgical PICU ☐ Cardiac SICU or PICU ☐ CCU ☐ Neuro ICU ☐ Burn ICU ☐ Trauma ICU ☐ Cancer Unit ☐ MICU/SICU ☐ NICU ☐ Other ____

Influenza Testing

Select all that apply; include all testing for influenza virus conducted during the ICU stay.

Data collection form on next page

1. Rapid Antigen Detection Tests done? Enter for all tests done (positive and negative)	☐ Done ☐Not done **If test done:** a. Date of test: ___/____/____ b. Specimen Tested (check one): ☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue c. Results (select all that apply): ☐Influenza A ☐Influenza B ☐Negative
2. Direct Fluorescent Antibody Test (DFA) Enter for all tests done (positive and negative)	☐ Done ☐Not done **If test done:** a. Date of test: ___/____/____ b. Specimen Tested (check one): ☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue c. Results (select all that apply): ☐Influenza A ☐Influenza B ☐Negative ☐Inconclusive or indeterminant
3. rtPCR Enter for all tests done (positive and negative)	☐ Done ☐Not done **If test done:** a. Date of test: ___/____/____ b. Specimen Tested (check one): ☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab

	☐Sputum ☐Mixed Specimen ☐Lung tissue c. Results (select all that apply): ☐ Novel A (H1N1) ☐ Seasonal A (H1N1) ☐ Seasonal A (H3N2) ☐ A, not subtyped ☐ B ☐ A/B not differentiated ☐Negative
4. Viral Culture Enter for all tests done (positive and negative)	☐ Done ☐Not done **If test done:** a. Date of test: ___/____/____ b. Specimen Tested (check one): ☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue c. Results (select all that apply): ☐ Novel A (H1N1) ☐ Seasonal A (H1N1) ☐ Seasonal A (H3N2) ☐ A, not subtyped ☐ B ☐ A/B not differentiated ☐Negative

Influenza testing data collection form

Rapid Antigen Detection Test/EIA		☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue	☐Influenza A ☐Influenza B ☐Negative
Rapid Antigen Detection Test/EIA		☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue	☐Influenza A ☐Influenza B ☐Negative
Rapid Antigen Detection Test/EIA		☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue	☐Influenza A ☐Influenza B ☐Negative
Rapid Antigen Detection Test/EIA		☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue	☐Influenza A ☐Influenza B ☐Negative
Direct Fluorescent Antibody Test (DFA)		☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue	☐Influenza A ☐Influenza B ☐Negative ☐Inconclusive or indeterminant
Direct Fluorescent Antibody Test (DFA)		☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue	☐Influenza A ☐Influenza B ☐Negative ☐Inconclusive or indeterminant
Direct Fluorescent Antibody Test (DFA)		☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab	☐Influenza A ☐Influenza B ☐Negative ☐Inconclusive or indeterminant

		☐Sputum ☐Mixed Specimen ☐Lung tissue	
Direct Fluorescent Antibody Test (DFA)		☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue	☐Influenza A ☐Influenza B ☐Negative ☐Inconclusive or indeterminant
rtPCR		☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue	☐ Novel A (H1N1) ☐ Seasonal A (H1N1) ☐ Seasonal A (H3N2) ☐ A, not subtyped ☐ B ☐ A/B not differentiated ☐Negative
rtPCR		☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue	☐ Novel A (H1N1) ☐ Seasonal A (H1N1) ☐ Seasonal A (H3N2) ☐ A, not subtyped ☐ B ☐ A/B not differentiated ☐Negative
rtPCR		☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue	☐ Novel A (H1N1) ☐ Seasonal A (H1N1) ☐ Seasonal A (H3N2) ☐ A, not subtyped ☐ B ☐ A/B not differentiated ☐Negative
rtPCR		☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue	☐ Novel A (H1N1) ☐ Seasonal A (H1N1) ☐ Seasonal A (H3N2) ☐ A, not subtyped ☐ B ☐ A/B not differentiated ☐Negative
Viral Culture		☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab ☐Sputum ☐Mixed Specimen ☐Lung tissue	☐ Novel A (H1N1) ☐ Seasonal A (H1N1) ☐ Seasonal A (H3N2) ☐ A, not subtyped ☐ B ☐ A/B not differentiated ☐Negative
Viral Culture		☐Nasal swab ☐Nasopharyngeal swab ☐Nasopharyngeal wash ☐Endotracheal aspirate ☐BAL ☐Throat swab	☐ Novel A (H1N1) ☐ Seasonal A (H1N1) ☐ Seasonal A (H3N2) ☐ A, not subtyped ☐ B

		☐Sputum ☐Mixed Specimen ☐Lung tissue	☐ A/B not differentiated ☐Negative

Section 2

Baseline Variables Form

Complete form once at baseline.

1. Gender:	☐ Male ☐ Female
2. Is patient age at time of ICU admission >2 years?	☐ Yes ☐ No If YES, enter age in years: ____ years If NO (patient < 2 years of age), enter age in months and days: ____ mos ____ days
3. Complete if patient is less than <u>1 year</u> of age at time of ICU admission: **a. Was patient born prematurely (less than 37 weeks gestation)?**	☐ Yes ☐ No If YES, enter number of weeks gestation at birth: _____ wks Corrected gestational age at identification of influenza: _____ wks
4. Ethnicity:	☐ Hispanic or Latino ☐ NOT Hispanic or Latino
5. Race: Select ALL that apply. **NOTE:** If the race(s) cannot be obtained, select **"not reported".**	
American Indian	☐
Alaskan Native	☐
Asian	☐
White (can be Hispanic or non-Hispanic)	☐
Black or African Native (can be Hispanic or non-Hispanic)	☐
Native Hawaiian or Pacifica Islander	☐
Not reported	☐
6. Healthcare worker?	☐ Yes ☐ No
7. Weight in kg:	_____ kg
8. Height in cm:	_____ cm
9. Influenza vaccination: Select yes, no or unknown for all vaccinations listed.	
a. 2008/09 Season	☐ Yes ☐ No ☐ Unknown
b. 2009/10 Season	☐ Yes ☐ No ☐ Unknown
c. Swine H1N1 Vaccination	☐ Yes ☐ No ☐ Unknown If YES, how many doses received? ☐ One ☐ Two ☐ Unknown

10. Is date of onset of initial influenza symptoms KNOWN?	☐ Yes ☐ No If YES (**KNOWN)**, enter date:
11. Clinical presentation on hospital admission day (select all that apply):	
Lower respiratory infection	☐
Suspected central nervous system infection	☐
Shock requiring vasopressors	☐
Respiratory failure	☐
Cardiac arrest	☐
12. Clinical Features: Features of Influenza Disease that patient experienced (select all that apply)**.** *Please include all symptoms leading to the current illness, regardless of when they occurred.*	
Fever $\geq$ 100 F or 37.7 C	☐
Cough	☐
Shortness of breath	☐
Chills	☐
Wheezing	☐
Sore throat	☐
Rhinorrhea	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Headache	☐
Myalgias	☐
Fatigue/Weakness	☐
Altered awareness/confusion	☐
Seizures	☐
13. Study Hospital admission date:	
14. Study hospital ICU admission date:	
14a. Patient Origin	☐ Emergency Dept (your hospital) ☐ Referring hospital Emergency Dept ☐ Ward (your hospital) ☐ Referring hospital ward ☐ Referring hospital ICU ☐ Operating room ☐ Direct from home ☐ Other
15. If Patient referred from another hospital, date of referral hospital admission:	
16. If Patient referred from another hospital, date of referral ICU admission (if applicable):	
17. Healthy prior to present illness? *(Prior to present illness, was patient healthy, on no prescriptions, without underlying medical*	☐ Yes ☐ No If no, complete co-morbidities (question 16).

conditions, and not dependent on any medical devices?)	
18. Co-Morbidities present prior to this illness: Select all co-morbidities that apply:	
Diabetes (Type I or II)	☐
Ischemic heart disease/Angina	☐
Other metabolic disorder (ACIP condition)	☐
Congenital heart disease	☐ If selected, ☐ Cyanotic, unrepaired or palliated ☐ Non-cyanotic or complete repair
Arrhythmia	☐
Hypertension	☐
Peripheral vascular disease	☐
Congestive heart failure	☐
Valvular heart disease	☐
Cerebrovascular disease	☐
COPD	☐
Asthma or reactive airway disease	☐ If selected, on weekly controller medications? ☐ Yes ☐ No
Bronchopulmonary dysplasia	☐
Other chronic lung disease (including severe restrictive lung disease)	☐
Gastrointestinal disease	☐
Cirrhosis of the liver	☐
Chronic renal insufficiency	☐
Cerebral palsy	☐
Developmental delay/cognitive disorder	☐
Seizure disorder	☐
Other neurological/neuromuscular disease that could impair clearance of secretions	☐
Spina bifida	☐
Sickle cell or other hemoglobinopathy	☐
Current (or active) Metastatic solid cancer	☐
Current (or active) Hematologic malignancy	☐
HIV	☐
Intravenous Drug Abuse (IVDA)	☐
Pregnant	☐
Renal failure requiring dialysis	☐
Other immunosuppression (such as bone marrow or organ transplant)	☐
Chronic ventilator support	☐ ≤ 12 hours per day ☐ > 12 hours per day
Tracheostomy	☐
19. Tobacco use (select one):	☐ Past smoker (i.e. Daily Tobacco use ever but not currently) ☐ Current Smoker (i.e. Daily Tobacco use during month prior to admission)

	☐ Secondhand Smoke (i.e. Current exposure to tobacco in house) ☐ None/Unknown
20. Alcohol abuse (select one)? **Answer if age > 12 years**	☐ Past ETOH abuse (i.e. Past abuse ever but not currently) ☐ Current ETOH abuse (i.e. >= 4 drinks per day) ☐ None/Unknown
21. Medications on hospital admission: Select all medications that patient was on **at home prior to admission.**	
Aspirin (any dose)	☐
Non-steroidal anti-inflammatories (ibuprofen, Naprosyn, etc.)	☐
Statin (i.e. atorvastatin, cerivastatin, fluvastatin, lovastatin, mevastatin, pitavastatin, pravastatin, rosuvastatin, simvastatin)	☐
Corticosteroids > 20mg/day prednisone equivalent for adults and > 0.3 mg/kg/day for patients < 18 years old **for any duration within 6 months of ICU admission?**	☐
Other immunosuppressives chemo, mtx, azathioprine, fk506, tacrolimus, sirilimus	☐
Angiotensin converting enzyme inhibitors (i.e. benazepril, captopril, enalapril, fosinopril, lisinopril, perindopril, quinapril, ramipril, zofenopril)	☐
Anti-influenzals (i.e. amantadine, oseltamivir, paramivir, rimantadine, zanamivir)	☐ If selected, enter date started:
22. APACHE II Score if age ≥ 18	
23. Baseline lab values (closest to ICU admission +/- 2 days): Enter available lab values fromCU admission day. If no values available on ICU admission day, select the values closest to ICU admission from **up to 2 days before and after ICU admission**.	
a. Creatinine	mg/dL
b. Total Bilirubin	mg/dL
c. CPK (creatinine phosphokinase)	U/L
d. WBC Count	mm^3
e. Polys (PMN/Neutrophils)	%
f. Lymphs	%
g. Eos	%
h. Mono/Mac	%
i. Other	%
j. Platelets	x 10^9/mL

PRISM SCORE

Obtain WORST values from the first 24 hours in the ICU.

1. Age category:	☐Neonate ☐Infant ☐Child ☐Adolescent
2. Systolic BP:	mmHg
3. Temperature:	C
4. Heart rate:	b/m
5. Pupillary reflexes:	☐N/A ☐1 fixed, 1 reactive ☐both fixed
6. GCS (lowest):	
7. Platelet count:	10^9/L
8. Total CO2:	
9. pH (alkalosis):	
10. PaO2:	mmHg
11. PaCO2:	mmHg
12. Glucose:	mg/dL
13. Potassium:	mEq/L
14. Creatinine:	mg/dL
15. BUN:	mg/dL
16. WBC:	cells/mm3
17. pH or CO2 (acidosis):	
18. PT or PTT:	seconds

Admission Assessment and Treatment Form

Complete this form for ICU admission day.
Use values closest to time following ICU admission (may use values right before admission if on transport or from the ED).

1. Temperature (Celsius)**:**	° Celsius
2. Heart rate:	Beats/min
3. Respiratory rate:	Beats/min
4. Systolic Blood Pressure	mmHg
5. Diastolic Blood Pressure	mmHg
6. Vasopressor dose at time of ICU admission?	☐None ☐Dopamine <5 ug/kg/min or dobutamine at any dose ☐Dopamine >/= 5 ug/kg/min or norepi/epi </=0.1 ug/kg/min or phenylephrine </= 0.5 ug/kg/min ☐Dopamine > 15 ug/kg/min or norepi/epi > 0.1 ug/kg/min or phenylephrine > 0.5 ug/kg/min
7. P/F (closest to ICU admission):	
8. SaO2/FiO2 closest to ICU admission: (if no P/F available on day of ICU admit) *Example: If SpO2 is 85 % on 100 % oxygen, the S/F is 85/1.00 or 85*	
9. Glasgow Coma Score: (3-15)	
10. Chest x-ray done on ICU admission day? (+/- 1 day)	☐ Yes ☐ No If YES, enter # of quadrants with infiltrates: _____
11. Did patient receive invasive ventilation on ICU admission day?	☐ Yes ☐ No
12. Did patient receive non-invasive ventilation on ICU admission day?	☐ Yes ☐ No
13. Is patient on DIALYSIS on ICU admission day?	☐ Yes ☐ No
14. Is patient on ECMO on ICU admission day?	☐ Yes ☐ No

Section 3: Intermittent Updates

Day Three Vital Status and Organ Failure Form

- Complete information for ICU day 3.
- Use available values closest to 8 AM.
- If the answer to question 2 = NO, then you do not need to complete the day 7, 14 or 28 vital status forms.
- If labs or other results are NOT available for day 3, leave blank.

1. Did patient receive Dialysis on any of ICU days 1-3?	☐ Yes ☐ No
2. Is patient still in the ICU?	☐ Yes ☐ No
a. If YES (still in ICU), did patient receive invasive ventilation on ICU day 3?	☐ Yes ☐ No
b. If YES (still in ICU), did patient receive non-invasive ventilation on ICU day 3?	☐ Yes ☐ No
c. If NO (not in ICU), was patient discharged from ICU alive or dead?* * If no longer in ICU**, complete d-f below** on this form and go to ICU Summary form	☐ Alive ☐ Dead
d. If discharged from ICU alive, date of ICU discharge:	Date:_____ **Did patient die after ICU d/c but before day 3?** ☐ Yes ☐ No
3. Creatinine:	mg/dL
4. Total Bilirubin:	mg/dL
5. Platelets:	x 10^9/mL
6. Systolic Blood Pressure	mmHg
7. Diastolic Blood Pressure	mmHg
8. Vasopressor dose at 0800 on ICU day 3:	☐None ☐Dopamine <5 ug/kg/min or dobutamine at any dose ☐Dopamine >/= 5 ug/kg/min or norepi/epi </=0.1 ug/kg/min or phenylephrine </= 0.5 ug/kg/min ☐Dopamine > 15 ug/kg/min or norepi/epi > 0.1 ug/kg/min or phenylephrine > 0.5 ug/kg/min

9. P/F closest to 0800 on day 3	
10. PEEP closest to 0800 on day 3	cm H20
11. SaO2/FiO2 closest to 0800 on day 3	
12. Glasgow Coma Score: (3-15)	
13. Did patient receive ECMO on any day during days 1-3?	☐ Yes ☐ No # days any ECMO_____

Day Seven Vital Status and Organ Failure Form

- Complete information for ICU day 7.
- Use available values closest to 8 AM.
- If the answer to question 2 = NO, then you do not need to complete the day 14 or 28 vital status forms.
- If labs or other results are NOT available for day 7, leave blank.

1. Did patient receive Dialysis on any day 4-7?	☐ Yes ☐ No
2. Is patient still in the ICU?	☐ Yes ☐ No
e. If YES (still in ICU), did patient receive invasive ventilation on ICU day 7?	☐ Yes ☐ No
f. If YES (still in ICU), did patient receive non-invasive ventilation on ICU day 7?	☐ Yes ☐ No
a. If NO (not in ICU), was patient discharged from ICU alive or dead?* * If no longer in ICU**, complete d-f below** on this form and go to ICU Summary form	☐ Alive ☐ Dead
b. If discharged from ICU alive, date of ICU discharge:	Date:_____ **Did patient die after ICU d/c but before day 7?** ☐ Yes ☐ No
3. Creatinine:	mg/dL
4. Total Bilirubin:	mg/dL
5. Platelets:	x 10^9/mL
6. Systolic Blood Pressure	mmHg
7. Diastolic Blood Pressure	mmHg
8. Vasopressor dose at 0800 on ICU day 7:	☐None ☐Dopamine <5 ug/kg/min or dobutamine at any dose ☐Dopamine >/= 5 ug/kg/min or norepi/epi </=0.1 ug/kg/min or phenylephrine </= 0.5 ug/kg/min ☐Dopamine > 15 ug/kg/min or norepi/epi > 0.1 ug/kg/min or phenylephrine > 0.5 ug/kg/min

9. P/F closest to 0800 on day 7	
10. PEEP closest to 0800 on day 7	cm H20
11. SaO2/FiO2 closest to 0800 on day 7 *Example: If SpO2 is 85 % on 100 % oxygen, the S/F is 85/1.00 or 85*	
12. Glasgow Coma Score: (3-15)	
13. Did patient receive ECMO on any day during days 4-7?	☐ Yes ☐ No # days any ECMO_____

Day 14 Vital Status and Organ Failure Form

- Complete information for ICU day 14.
- Use available values closest to 8 AM.
- If the answer to question 2 = NO, then you do not need to complete the day 28 vital status forms.
- If labs or other results are NOT available for day 14, leave blank.

1. Did patient receive Dialysis on any days 8-14?	☐ Yes ☐ No
2. Is patient still in the ICU?	☐ Yes ☐ No
g. If YES (still in ICU), did patient receive invasive ventilation on ICU day 14?	☐ Yes ☐ No
h. If YES (still in ICU), did patient receive non-invasive ventilation on ICU day 14?	☐ Yes ☐ No
a. If NO (not in ICU), was patient discharged from ICU alive or dead?* * If no longer in ICU**, complete d-f below** on this form and go to ICU Summary form	☐ Alive ☐ Dead
b. If discharged from ICU alive, date of ICU discharge:	Date:_____ **Did patient die after ICU d/c but before day 14?** ☐ Yes ☐ No
3. Creatinine:	mg/dL
4. Total Bilirubin:	mg/dL
5. Platelets:	x 10^9/mL
6. Systolic Blood Pressure	mmHg
7. Diastolic Blood Pressure	mmHg
8. Vasopressor dose at 0800 on ICU day 14:	☐None ☐Dopamine <5 ug/kg/min or dobutamine at any dose ☐Dopamine >/= 5 ug/kg/min or norepi/epi </=0.1 ug/kg/min or phenylephrine </= 0.5 ug/kg/min ☐Dopamine > 15 ug/kg/min or norepi/epi > 0.1 ug/kg/min or phenylephrine > 0.5 ug/kg/min

9. P/F closest to 0800 on day 14	
10. PEEP closest to 0800 on day 14	cm H20
11. SaO2/FiO2 closest to 0800 on day 14 *Example: If SpO2 is 85 % on 100 % oxygen, the S/F is 85/1.00 or 85*	
12. Glasgow Coma Score: (3-15)	
13. Did patient receive ECMO on any day during days 8-14?	☐ Yes ☐ No # days any ECMO_____

Day 28 Vital Status

Complete for ICU day 28.
Please complete ICU Summary form once this form complete.

1. **Is patient still in the ICU?**	☐ Yes ☐ No
2. If NO (not in ICU), was patient discharged from ICU alive or dead?	☐ Alive ☐ Dead
3. If discharged from ICU alive, date of ICU discharge:	Date:_____ **Did patient die after ICU d/c but before day 28?** ☐ Yes ☐ No

Severe Hypoxia

Complete for all subjects after ICU day 7.
If question 1= NO, form complete.

1. Did patient receive PEEP of >/= 15 for 2 or more consecutive hours between ICU admit and ICU day 7? **or** Was patient on high-frequency oscillatory ventilation with mean airway pressure >/=30 for 2 or more consecutive hours between ICU admit and ICU day 7?	☐ No ☐ PEEP >/= 15 ☐ HFOV with MAP >/= 30
2. HIGHEST PEEP between ICU admit and ICU day 7 (which occurred during a 2 hour period of PEEP >=15)? **OR** If on high-frequency oscillatory ventilation during that time, what was the highest mean airway pressure between ICU admit and ICU day 7 (which occurred during a 2 hour period of mean airway pressure >=30)?	_____ cm H2O
3. Mode of ventilation:	[] Assist-control (A/C), controlled mechanical ventilation (CMV), or pressure-regulated volume control (PRVC) [] Pressure control (PCV) [] Pressure support (PSV) [] Continuous positive airway pressure (CPAP) [] High-frequency ventilation (HFOV) [] Other (specify):
4. Highest FiO2	
5. Closest PaO2 in the 3 hours before and after the FiO2 in previous question:	
6. Closest SaO2 (if no PaO2) in the 3 hours before and after the FiO2:	
7. Plateau pressure if on volume ventilation (A/C, CMV, or PRVC) **or** End inspiratory pressure if on pressure targeted ventilation (PCV, PSV, or CPAP)	
8. Mean airway pressure (if on HFOV)	
9. Did the following occur at any time between ICU admit and the time of PEEP >=15 for at least 2 consecutive hours or HFOV with mean alveolar pressure >=30 for at least 2 hours? (select all that apply)	:_____ Highest aPTT(seconds): _____ Lowest platelets ($x10^9$/ml):_____ [] Known hemorrhage [] Not committed to full support [] Irreversible brain injury

ICU Summary Form

Complete when patient is deceased, is discharged from the ICU, or on ICU day 28 (whichever occurs first).

1. Was influenza confirmed by positive laboratory test?	☐ Yes ☐ No If YES, **please update Section 1 of CRF.**
Respiratory Summary	
2. Date of first Intubation or initiation of mechanical ventilation through trach?	__/____/_____ ☐ Never Intubated
3. Date of final Extuba**tion?**	__/____/_____ ☐ Never Extubated
3a. Total Days on Noninvasive Ventilation at any time PRIOR TO intubation *Use decimals for partial days*	_____ ☐ None
3b. Total Days on Noninvasive Ventilation at any time AFTER extubation *Use decimals for partial days*	_____ ☐ None
4. Was patient ever re-admitted to the ICU after the initial ICU discharge?	☐ Yes ☐ No ☐ N/A If Yes, Date of re-admit:
Reason for re-admit:	☐ Lower respiratory infection ☐ Suspected central nervous system infection ☐ Shock requiring vasopressors ☐ Respiratory failure ☐ Cardiac arrest ☐ Other:_____
Was patient discharged from ICU a second time?	☐ Yes ☐ No If yes, Date of d/c:
5. Was patient re-admitted again to the ICU?	☐ Yes ☐ No If Yes, Date of re-admit:
Reason for re-admit:	☐ Lower respiratory infection ☐ Suspected central nervous system infection ☐ Shock requiring vasopressors ☐ Respiratory failure ☐ Cardiac arrest ☐ Other:_____
Was patient discharged again from ICU?	☐ Yes ☐ No If yes, Date of d/c:
6. Empyema requiring thoracostomy drainage or VATS?	☐ Yes ☐ No

7. Clinical Diagnosis of Bacterial Pneumonia or superinfection?	☐ Yes ☐ No
a. If **question #5 yes,** was diagnosis of bacterial pneumonia or other evidence of bacterial superinfection present within 72 hours of ICU admission?	☐ Yes ☐ No
b. If **question #5 yes,** was bacterial pathogen identified from respiratory secretions?	☐ Yes ☐ No If yes, date of positive culture: ___/___/___ **If yes, select Yes or no for each pathogen:** ☐ Staph aureus (methicillin resistant) ☐ Staph aureus (methicillin sensitive) ☐ Group A strep ☐ Strep pneumoniae ☐ Pseudomonas Species ☐ Hemophilus influenza ☐ M.cattarhalis ☐ RSV ☐ Other Virus ☐ other_____
5a Any positive non-influenza viral tests within the first 72 hours of admission	☐ RSV ☐ Parainfluenza ☐ Human metapneumovirus ☐ Adenovirus ☐ Other Virus
5b Was the patient diagnosed with a nosocomial infection during the ICU stay to day 28 using CDC, NACHRI or other surveillance definitions?	☐ Yes ☐ No If Yes: ☐ Ventilator associated pneumonia ☐ Secondary viral lower respiratory infection ☐ Catheter associated bloodstream infection ☐ Urinary tract infection
Non-Respiratory Summary	
8. Any positive <u>blood culture</u> for bacteria in the first 72 hours of admission??	☐ Yes ☐ No If yes, indicate pathogen(s): ☐ Staph aureus (methicillin resistant) ☐ Staph aureus (methicillin sensitive) ☐ Group A strep ☐ Strep pneumoniae ☐ Pseudomonas Species ☐ Hemophilus influenza ☐ M.cattarhalis ☐ Other Virus ☐ other_____

9. Echo done during first 5 days of hospital stay?	☐ Yes ☐ No **If yes:** Worst LVEF _____% Highest RVSP _____ (mmHg)
10. Seizure during ICU stay?	☐ Yes ☐ No
11. Was the patient diagnosed with myocarditis?	☐ Yes ☐ No If yes, was myocarditis the major clinical diagnosis underlying the patient's reason for ICU admission? ☐ Yes ☐ No
12. Encephalitis by MRI or high CSF protein or clinical diagnosis by neurologist?	☐ Yes ☐ No
13. Confirmed deep venous thrombosis or pulmonary embolism during hospital stay?	☐ Yes ☐ No If yes, was this related to a central venous catheter? ☐ Yes ☐ No
14. Did patient receive tracheostomy during ICU stay?	☐ Yes ☐ No
15. Was patient on dialysis on day 28 or ICU DC	☐ Yes ☐ No
16. Was patient pregnant on admission?	☐ Yes ☐ No If YES, indicate outcome of pregnancy: ☐ Spontaneous abortion/miscarriage ☐ Maintained intrauterine viable fetus ☐ Normal vaginal delivery ☐ Caesarean delivery If Vaginal or Caesarean delivery did infant survive to hospital d/c? ☐ Yes ☐ No Was the infant term (i.e. >36wks) ☐ Yes ☐ No
17. Experimental/Adjunctive therapies received during ICU stay? (Pick all that apply)	
a. Nitric oxide or inhaled epoprostenol	☐ Yes ☐ No
b. ECMO and variants	☐ Yes ☐ No # days_____
c. High Frequency Ventilation	☐ Yes ☐ No # days_____
d. High dose corticosteroids at any time excluding for airway edema around extubation: >= 2 mg/kg/day methylprednisolone or prednisone or stress dose hydrocortisone	☐ Yes ☐ No

>= 0.5 mg/kg/day dexamethasone	
e. Prone ventilation	☐ Yes ☐ No
f. Drotrecogin-alfa (activated)	☐ Yes ☐ No
g. Intravenous Immune globulin (IVIG)	☐ Yes ☐ No
h. Intravenous Immune plasma	☐ Yes ☐ No
i. Fresh frozen plasma (for any indication)	☐ Yes ☐ No
16. Highest Total CPK during hospitalization:	U/L ☐ Not measured
17. Highest Troponin level during hospitalization:	_____ ☐ Not measured
18. Highest creatinine value during hospitalization:	_____ mg/dL
19. Highest bilirubin value during hospitalization:	_____ mg/dL
20. Lowest platelet value during hospitalization:	_____ x 10^9/mL

Section 4

Antiviral Form

Select yes or no to indicate whether these antivirals were administered **during the ICU stay.** If yes, indicate the **number of ICU days** each medication was administered and indicate all routes that apply.

1. Oseltamivir (Tamiflu)	☐ Yes ☐ No If YES, a. Enter # of ICU days antiviral received: ____ b. Select route (select all that apply): ☐ IV ☐ Oral/enteral ☐ Inhaled c. Average Daily Dose ☐ 75 mg bid ☐ 150 mg bid ☐ Other: _____mg/kg/day
2. Zanamivir (Relenza)	☐ Yes ☐ No If YES, a. Enter # of ICU days antiviral received: ____ b. Select route (select all that apply): ☐ IV ☐ Oral/enteral ☐ Inhaled
3. Peramivir	☐ Yes ☐ No If YES, a. Enter # of ICU days antiviral received: ____ b. Select route (select all that apply): ☐ IV ☐ Oral/enteral ☐ Inhaled
4. Amantadine (Symmetrel)	☐ Yes ☐ No If YES, a. Enter # of ICU days antiviral received: ____ b. Select route (select all that apply): ☐ IV ☐ Oral/enteral ☐ Inhaled
5. Rimantadine (Flumadine)	☐ Yes ☐ No If YES, a. Enter # of ICU days antiviral received: ____ b. Select route (select all that apply): ☐ IV ☐ Oral/enteral ☐ Inhaled

6. Ribavirin	☐ Yes ☐ No If YES, c. Enter # of ICU days antiviral received: ____ d. Select route (select all that apply): ☐ IV ☐ Oral/enteral ☐ Inhaled
7. Other influenza antiviral	☐ Yes ☐ No If YES, Name of antiviral _____ a. Enter # of ICU days antiviral received: ____ b. Select route (select all that apply): ☐ IV ☐ Oral/enteral ☐ Inhaled

Section 5

Hospital Outcomes to Day 90

Complete for all patients.

1. Still alive and in study hospital at day 90? (if yes, answer and then skip questions below)	☐ Yes ☐ No If yes, still in ICU? ☐ Yes, in ICU ☐ No, stepdown or intermediate care unit ☐ No, hospital ward
2. Discharged alive from study hospital on or before day 90?	☐ Yes ☐ No If yes, date of hospital discharge: If yes, discharged to: ☐ Home ☐ Other acute hospital ☐ Rehabilitation hospital ☐ Other
3. Deceased in study hospital on or before day 90? **Was an autopsy performed? If yes, please fax a deidentified copy or attach as pdf**	☐ Yes ☐ No If yes, date of death: __/____/_____ ☐ Yes ☐ No
4. Cause of death (if applicable):	☐ Primary respiratory ☐ Primary cardiac ☐ Multiorgan Failure ☐ Brain death or severe brain injury ☐ Other _____
5. Was the patient's death thought to be related to the influenza infection?	☐ Definitely related – death was a direct result of complications from the initial infection ☐ Possibly related ☐ Unrelated (recurrent malignancy, died of fatal, progressive underlying chronic condition) ☐ Unsure