H1N1 Case Report Form: ADULT Table of Contents

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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 three digits represent site number the second three digits are the chronologic patient number. Example: if you are site 999 and you are entering your ninth H1N1 subject, the subject number will be 999009.
 - 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 <u>stop light</u> in front of the form you wish to complete will open the form for that patient. *NOTE:* clicking on the <u>text</u> 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.

Case Definition and ICU Location

Complete form at baseline.

Case definition: please choose confirmed or suspected.	
A <i>confirmed case</i> 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	☐ Confirmed case
A <i>suspected case</i> 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 antivirals 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 <i>Legionella pneumophila</i>)) then the person should NOT be considered a suspected case for this registry.	☐ 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 ICU admit day.	MICU or PICU SICU or Surgical PICU Cardiac SICU or PICU CCU Neuro ICU Burn ICU Trauma ICU Cancer Unit
location on ICU admit day.	☐ MICU/SICU ☐ NICU ☐ Other

Influenza Testing

Select all that apply; include $\underline{all\ testing}$ for influenza virus conducted during the ICU stay.

Data collection form on next page

Data concetion form of flext page	
1. Rapid Antigen Detection Tests done?	☐ Done ☐ Not done
	If test done:
Enter for all tests done (positive and negative)	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
	g .
	c. Results (select all that apply):
	☐Influenza A
	☐Influenza B
	□Negative
Direct Fluorescent Antibody Test (DFA)	☐ Done ☐ Not done
Direct Fluorescent Antibody Test (DFA)	If test done:
Direct Fluorescent Antibody Test (DFA) Enter for all tests done (positive and negative)	
,	If test done:
,	If test done: a. Date of test:// b. Specimen Tested (check one): Nasal swab
,	If test done: a. Date of test:// b. Specimen Tested (check one):
,	If test done: a. Date of test:// b. Specimen Tested (check one):
,	If test done: a. Date of test:// b. Specimen Tested (check one):
,	If test done: a. Date of test:/ b. Specimen Tested (check one):
,	If test done: a. Date of test:// b. Specimen Tested (check one):
<u> </u>	If test done: a. Date of test:// b. Specimen Tested (check one):
<u> </u>	If test done: a. Date of test:// b. Specimen Tested (check one):
,	If test done: a. Date of test:// b. Specimen Tested (check one):
,	If test done: a. Date of test:// b. Specimen Tested (check one):
,	If test done: a. Date of test:// b. Specimen Tested (check one):
,	If test done: a. Date of test:/
,	If test done: a. Date of test:// b. Specimen Tested (check one):

0 1000	Dono Duck dono
3. rtPCR	☐ Done ☐ Not done If test done:
	a. Date of test://
Enter for all tests done (positive and negative)	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	☐ Done ☐ Not done
	If test done:
Enter for all tests done (positive and negative)	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

See data collection form on next page.

Influenza testing data collection form

Test	Date of test	Specimen Tested	Results
Rapid Antigen	Date of test	Nasal swab	Influenza A
		□ Nasopharyngeal swab	☐Influenza B
Detection Test		☐Nasopharyngeal wash	Negative
		☐Endotracheal aspirate	Писдание
		□BAL	
		☐Throat swab	
		Sputum Miyad Specimen	
		☐Mixed Specimen☐Lung tissue	
Danid Antigan		□ Nasal swab	☐Influenza A
Rapid Antigen Detection Test		☐Nasopharyngeal swab	☐Influenza B
Detection rest		☐Nasopharyngeal wash	Negative
		☐Endotracheal aspirate	Писдание
		BAL	
		Throat swab	
		☐ Sputum ☐ Mixed Specimen	
		Lung tissue	
Rapid Antigen		□ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □	☐Influenza A
Detection Test		☐Nasopharyngeal swab	☐Influenza B
Detection rest		☐Nasopharyngeal wash	Negative
		☐Endotracheal aspirate	Подите
		□BAL	
		☐Throat swab ☐Sputum	
		☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	
		Lung tissue	
Rapid Antigen		□ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □ □	☐Influenza A
Detection Test		☐Nasopharyngeal swab	☐Influenza B
Detection rest		☐Nasopharyngeal wash	Negative
		Endotracheal aspirate	Поданто
		BAL	
		☐Throat swab ☐Sputum	
		☐Mixed Specimen	
		Lung tissue	
Direct		□Nasal swab	☐Influenza A
Fluorescent		☐Nasopharyngeal swab	☐Influenza B
Antibody Test		■Nasopharyngeal wash	Negative
_		Endotracheal aspirate	
(DFA)		BAL	
		☐Throat swab ☐Sputum	
		☐Mixed Specimen	
		Lung tissue	
Direct		□Nasal swab	☐Influenza A
Fluorescent		☐Nasopharyngeal swab	☐Influenza B
		□Nasopharyngeal wash	Negative
Antibody Test		☐ Endotracheal aspirate	
(DFA)		BAL Throat sweb	
		☐Throat swab ☐Sputum	
		☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	
		Lung tissue	
	I	L — Eding 1133dc	

Test	Date of test	Specimen Tested	Results
Direct Fluorescent Antibody Test		☐ Nasal swab☐ Nasopharyngeal swab☐ Nasopharyngeal wash☐ Endotracheal aspirate	☐Influenza A ☐Influenza B ☐Negative
(DFA)		☐BAL ☐Throat swab ☐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
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

Test	Date of test	Specimen Tested	Results
Viral Culture			□ Novel A (H1N1) □ Seasonal A (H1N1) □ Seasonal A (H3N2) □ A, not subtyped □ B □ A/B not differentiated □ Negative

Baseline Variables Form

Complete form once at baseline.

1.	Gender:	F] Male] Female
2.	Patient age in years:	_	years
	<u> </u>	〒	Hispanic or Latino
3.	Ethnicity:		NOT Hispanic or Latino
4.	Race:		
	Select ALL that apply.		
	NOTE: If the race(s) cannot be obtained, select	"no	nt renorted"
	American Indian	T <u>::`</u>	
	Alaskan Native		
	Asian		
	White (can be Hispanic or non-Hispanic)		
	Black or African Native (can be Hispanic or	Г]
	non-Hispanic) Native Hawaiian or Pacifica Islander	_	1
	Native Hawaiian of Pacifica Islander Not reported	┢	
5.	Healthcare worker?	┢	Yes No
6.	Weight in kg:		kg
7.	Height in cm:		cm
8.	Influenza vaccination:		
	Select yes, no or unknown for all vaccina	tior	
	a. 2008/09 Season	Ļ	Yes No Unknown
	b. 2009/10 Season	ŀ⊨	Yes No Unknown
		L	Yes No Unknown
	c. Swine H1N1 Vaccination	lf	YES, how many doses received?
		Ë	One Two Unknown
9.	Is date of onset of initial influenza		Yes No
10	symptoms KNOWN?	If	YES (KNOWN), enter date:
10	. Clinical presentation on study hospital admission day (select all that apply):		
	Lower respiratory infection		
	Suspected central nervous system infection		
	Shock requiring vasopressors		
	Respiratory failure		
	Cardiac arrest		
11	. Clinical Features:		
	Features of Influenza Disease that patier	nt e	xperienced (select all that apply).
	Fever <u>> 100 F or 37.7 C</u>	누	<u>]</u>
	Cough		

Shortness of breath	
Chills	
Wheezing	
Sore throat	
Rhinorrhea	
Nausea	
Vomiting	
Diarrhea	
Headache	
Myalgias	
Fatigue/Weakness	
Altered awareness/confusion	
Seizures	
	T
12. Study hospital admission date:	
13. ICU admission date ():	
14. Healthy prior to present illness?	Yes No
(Prior to present illness, was patient healthy,	If no, complete co-morbidities (question 16).
on no prescriptions, without underlying medical	
conditions, and not dependent on any medical	
devices?)	
15. Co-Morbidities:	
Select all co-morbidities that apply:	
Diabetes (Type I or II)	
Ischemic heart disease/Angina	
Congenital heart disease	
Arrhythmia	
Hypertension	
Peripheral vascular disease	
Congestive heart failure	
Valvular heart disease	
Cerebrovascular disease	
COPD	
Asthma	
Bronchopulmonary dysplasia Other chronic lung disease	
Gastrointestinal disease	
Cirrhosis of the liver	
Chronic renal insufficiency	
Cerebral palsy/Developmental delay	
Seizure disorder	
Other neurological/neuromuscular disease	
that could impair clearance of secretions	
Spina bifida	
Sickle cell disease	
Current (or active) Metastatic solid cancer	
Current (or active) Hematologic malignancy	
HIV	
Intravenous Drug Abuse (IVDA)	

Drognant	П
Pregnant Renal failure requiring dialysis	
Other immunosuppression (such as bone	
marrow or organ transplant)	
16. 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
17. 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
18. Medications on hospital admission: Select all medications that patient was o	n 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?	
20 mg methylprednisolone equivalents: ≥3.75 mg dexamethasone	
≥3.75 mg dexamethasone ≥20 mg methylprednisolone	
≥25 mg metnyipieumsoione ≥25 mg prednisone	
≥100mg hydrocortisone	
Other immunosuppressives	
chemo, mtx, azathioprine, fk506, tacrolimus,	
sirilimus Angiotopsin converting on type inhibitors	
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:
19. APACHE II Score if age > 18	
Obtain worst values from the first 24 hours in the ICU. The WORST values are those that result in the highest number of points.	

20. PRISM III Score if age < 18 Obtain worst values from the first 24 hours in the ICU

21. Baseline lab values (closest to ICU admission +/- 2 days):

Enter available lab values fromICU admission day. If no values available on ICU admit 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

Admission Assessment and Treatment Form

Complete this form for day of ICU admission.

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 admit day? (+/- 1 day)	Yes No If YES, enter # of quadrants with infiltrates:	
11. Is patient on assisted breathing on ICU admit day?	☐ Yes ☐ No	
12. Did patient receive non-invasive ventilation on ICU admit day?	☐ Yes ☐ No	
13. Is patient on RRT on ICU admit day?	☐ Yes ☐ No	

Section 3: Intermittent Updates

ICU Day Three Vital Status and Organ Failure Form

Complete information for ICU day 3. Use available values closest to 8 AM.

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), is patient on assisted breathing?	☐ Yes ☐ No
b. If YES (still in ICU), did patient receive non-invasive ventilation?	☐ 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 If yes, complete question e. and f.
e. If deceased, date of death:	
f. Cause of death: Ask if autopsy was performed and fax a deidentified copy or attach as pdf	☐ Primary respiratory ☐ Primary cardiovascular ☐ Multiorgan failure ☐ Brain Death or severe brain injury ☐ Other If other, please specify
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	
Example: If SpO2 is 85 % on 100 % oxygen, the S/F is 85/1.00 or 85	
12. Glasgow Coma Score:	
(3-15)	

ICU Day Seven Vital Status and Organ Failure Form

Complete information for ICU day 7. Use available values closest to 8 AM.

1. Did patient receive Dialysis on any day 4-7?	☐ Yes ☐ No
2. Is patient still in the ICU?	☐ Yes ☐ No
a. If YES (still in ICU), is patient on assisted breathing?	Yes No
b. If YES (still in ICU), did patient receive non-invasive ventilation?	☐ 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 7? Yes No If yes, complete question e. and f.
e. If deceased, date of death:	
f. Cause of death: Ask if autopsy was performed and fax a deidentified copy or attach as pdf	Primary respiratory Primary cardiovascular Multiorgan failure Brain Death or severe brain injury Other If other, please specify
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)	

ICU Day 14 Vital Status and Organ Failure Form

Complete information for ICU day 14. Use available values closest to 8 AM.

Did patient receive Dialysis on any days 8-14?	☐ Yes ☐ No
2. Is patient still in the ICU?	☐ Yes ☐ No
a. If YES (still in ICU), is patient on assisted breathing?	☐ Yes ☐ No
b. If YES (still in ICU), did patient receive non-invasive ventilation?	☐ 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
	Date:
d. If discharged from ICU alive, date of ICU discharge:	Did patient die after ICU d/c but before day 14? Yes No If yes, complete question e. and f.
e. If deceased, date of death:	n joo, complete queetien et ana n
f. Cause of death: Ask if autopsy was performed and fax a deidentified copy or attach as pdf	☐ Primary respiratory ☐ Primary cardiovascular ☐ Multiorgan failure ☐ Brain Death or severe brain injury ☐ Other If other, please specify
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)	

ICU 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 If yes, complete question 4 and 5.
4. If deceased, date of death:	
5. Cause of death: Ask if autopsy was performed and fax a deidentified copy or attach as pdf	☐ Primary respiratory ☐ Primary cardiovascular ☐ Multiorgan failure ☐ Brain Death or severe brain injury ☐ Other If other, please specify

ICU Summary Form

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

Was patient also enrolled in either the SAILS or EDEN trial?	Yes No If yes, enter ARDSNet study number: ————————————————————————————————————
2. Was influenza confirmed by positive laboratory test?	☐ Yes ☐ No If YES, please update Section 1 of CRF.
Respiratory Summary	
3. Date of Intubation?	// Never Intubated
4. Date Extubated?	// Never Extubated
5. Empyema requiring thoracostomy drainage or VATS?	☐ Yes ☐ No
6. 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? Non-Respiratory Summary	Yes

7. 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. Eako dono during first E dove of	☐ Yes ☐ No
8. Echo done during first 5 days of hospital stay?	If yes: Worst LVEF% Highest RVSP (mmHg)
9. Seizure during ICU stay?	☐ Yes ☐ No
10. Was the patient diagnosed with myocarditis?	Yes No
11. Encephalitis by MRI or high CSF	☐ Yes ☐ No
protein or clinical diagnosis by	
neurologist? 12. Confirmed deep venous thrombosis or	
pulmonary embolism during hospital stay?	Yes No
13. Did patient receive tracheostomy during ICU stay?	☐ Yes ☐ No
14. Was patient on dialysis on day 28 or ICU DC	☐ Yes ☐ No
100 00	Yes No
15. Was patient pregnant on admission?	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
16. Experimental/Adjunctive therapies received during ICU stay? (Pick all that apply)	
a. Nitric oxide or inhaled	Yes No
epoprostenol	
b. ECMO and variants	Yes No

c. High Frequency Ventilation	☐ Yes ☐ No
d. High dose corticosteroids at any	Yes No
time:	
>= 100 mg/day methylprednisolone or	
>= 125 mg/day prednisone or	
>= 500 mg/day hydrocortisone or	
>= 20mg/day dexamethasone	
e. Prone ventilation	Yes No
f. Drotrecogin-alfa (activated)	☐ Yes ☐ No
g. Intravenous Immune globulin	Yes No
(IVIG)	
h. Intravenous Immune plasma	Yes No
i. Fresh frozen plasma (for any	☐ Yes ☐ No
indication)	☐ fes ☐ NO
17. Highest Total CPK during hospitalization:	U/L Not measured
18. Highest Troponin level during	□ Not massured
hospitalization:	Not measured
19. Highest creatinine value during	ma/dl
hospitalization:	mg/dL
20. Highest bilirubin value during	
hospitalization:	mg/dL
21. Lowest platelet value during	10 \ 0 /
hospitalization:	x 10^9/mL

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.

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:
2. Zanamivir (Relenza)	
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

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

Hospital Outcomes to Day 60

Complete only for patients still in the HOSPITAL beyond ICU day 28.

Discharged alive from hospital between days 28 and 60?	Yes No If yes, date of hospital discharge:
Deceased between days 28 and 60? Ask if autopsy was performed and fax a de-identified copy or attach as pdf	Yes No If yes, data of death:
3. Still alive and in study hospital at day 60?	☐ Yes ☐ No
4. Cause of death (if applicable):	Primary respiratory Primary cardiovascular Multiorgan failure Brain Death or severe brain injury Other If other, please specify