ADJUVANT STEROIDS IN ADULTS WITH PANDEMIC INFLUENZA (ASAP)

CASE RECORD FORM

Participant Initials: | | | |

Participant Trial ID: | | | | | |

Sponsor: Nottingham University Hospitals NHS Trust

(For worksheet only)

Date of Randomisation: __ __/__ __ __/__ __ __ __

Week 5 date: __ __/__ __ __/__ __ __ __

Day 90 date: __ __/__ __ __/__ __ __ __

REGISTRATION	
Participant Trial ID (Derived from Registration system)	☐☐☐☐☐
Participant Initials: (Derived from Registration system)	☐☐☐
Participant Date of birth: (Derived from Registration system)	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY
Participant Gender: (Derived from Registration system)	Male ☐ Female ☐
Type of consent at enrolment (Derived from Registration system)	**Written consent from participant** ☐ **Clinician decision** ☐
Date study medication dispensed to participant: (Derived from Registration system)	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY
Time study medication dispensed to participant: (Derived from Registration system)	☐☐ : ☐☐ Unknown ☐ 24 Hr Clock - HH:MM

Participant initials: ☐☐☐ **Participant Trial ID:** ☐☐☐☐☐	Screening/Enrolment to Day 5 (Visit 1)

HOSPITAL ADMISSION			
Date admitted to hospital:	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY		
Time admitted to hospital:	☐☐ : ☐☐ 24 Hr clock - HH:MM	Unknown ☐	
Date of onset of flu symptoms:	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY	Unknown ☐	
Participant unconscious at admission?	No ☐	Yes ☐	Not documented ☐
Participant confused/mentally disoriented at admission?	No ☐	Yes ☐	Not documented ☐
Participant received antiviral flu medication pre-admission (previous 7 days)? (tick one only)	No ☐	Yes ☐	Not documented ☐
Participant received antibiotics pre-admission (previous 7 days)? (tick one only)	No ☐	Yes ☐	Not documented ☐
If female, was participant pregnant?	No ☐	Yes ☐	Not documented ☐

MEDICAL HISTORY

Did the patient have any documented medical conditions at the time of hospital admission?	**No** ☐	**Yes** ☐	
If yes, was the participant documented as having any of the following conditions at the time of hospital admission?			
Medical History Term	**No**	**Yes**	**Unsure**
Obesity	☐	☐	
Asthma	☐	☐	
Chronic Obstructive Pulmonary Disease (COPD)	☐	☐	
Heart Disease	☐	☐	
HIV/AIDS	☐	☐	
Cancer (excluding melanoma and basal cell carcinoma)	☐	☐	☐
If Unsure if condition is cancer please provide details:	_____		
Confirmed cancer diagnosis? (NCTU use only)	☐	☐	
Any other ongoing medical condition?	☐	☐	

Participant initials: ☐☐☐ **Participant Trial ID:** ☐☐☐☐☐	Screening/Enrolment to Day 5 (Visit 1)

ADMISSION TESTS	
MEASUREMENT	**RESULT**
Body Temperature (º C)	☐☐ . ☐
Pulse/Heart rate (beats/min)	☐☐☐
Blood Pressure (Systolic/Diastolic) (mm/Hg)	☐☐☐ / ☐☐☐
Respiratory rate (Breaths/min)	☐☐
Oxygen Saturation (Pulse Oximetry) (%)	☐☐☐
Receiving supplementary oxygen at time of test? (tick one only)	No ☐ Yes ☐
If yes, how much? (tick one only)	☐☐☐ L/min ☐ **or** ☐☐☐ FiO_2 ☐

BLOOD TESTS		
Was a blood test taken on admission? (tick one only)	No ☐	Yes ☐
If yes, date and time of blood sample received at lab (enter first sample taken during hospital admission)	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY	☐☐ : ☐☐ 24 Hr clock - HH:MM
White cell count (WCC, WBC, leucocytes) (X 10^9/L)	☐☐☐ . ☐	Not available ☐
Urea (mmol/L)	☐☐☐ . ☐	Not available ☐
C-reactive protein (CRP) (mg/L)	☐☐☐	Not available ☐

Participant initials: ☐☐☐ **Participant Trial ID:** ☐☐☐☐☐	Screening/Enrolment to Day 5 (Visit 1)

CHEST X RAY			
Was a chest X-ray performed during the initial hospitalisation? (tick one only)	No ☐	Yes ☐	
If yes, date of first X-ray performed	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY	☐☐ : ☐☐ 24 Hr clock - HH:MM	
Is result of X-ray available?	Result awaited ☐	Result available ☐	
If available, findings of chest X-ray report (tick one only)	Normal ☐	Abnormal, pneumonia ☐	Abnormal, not pneumonia ☐

FLU CONFIRMATION			
Result of microbiological test for flu (tick one only)	Negative ☐	Positive ☐	Not Tested ☐

STUDY MEDICATION DOSE ADMINISTRATION	
How many doses of study medication did the participant receive whilst in hospital?	0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ Unknown ☐
If < 5, reason: (tick one only)	Participant discharged home to complete study medication ☐ Clinical decision to discontinue study medication ☐ Participant refused study medication ☐ Study medication lost/misplaced ☐ Other ☐ If Other, specify _____

CONCOMITANT MEDICATION			
Were antibiotics given to participant within the first 5 days of initial admission? (tick one only)	No ☐	Yes ☐	Unknown ☐
Was antiviral medication for flu given to participant within first 5 days of initial admission? (tick one only)	No ☐	Yes ☐	Unknown ☐
Were steroids given to the participant within the first 5 days of initial admission? (tick one only)	No ☐	Yes ☐	Unknown ☐
Were steroids prescribed for the participant between days 6-10 after initial admission?	No ☐	Yes ☐	Unknown ☐

TREATMENT FOR PNEUMONIA			
Was the participant treated clinically for pneumonia? (tick one only)	No ☐	Yes ☐	Unknown ☐

Participant initials: ☐☐☐ **Participant Trial ID:** ☐☐☐☐☐	Week 5 Status (Visit 2)

☐ **Tick if checks not performed (participant withdrawn consent prior to day 30)**
Please complete withdrawal form
Hyperlink to Withdrawal form

Derived Week 5 date:	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY
Date week 5 check performed:	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY

WEEK 5 CHECKS

A search of your hospital admission systems must be performed at the end of week 5 to check whether the participant has had any subsequent hospitalisations during this period.

Do the hospital records indicate the participant has died? (if yes please complete the death form)	No ☐ Yes ☐

HOSPITAL ADMISSIONS	
Was the participant transferred from this hospital to another hospital during first 5 weeks after admission? *Hyperlink to Admissions form*	No ☐ Yes ☐
Please confirm all known hospitalisations within 5 weeks of enrolment have been recorded on the Hospital Admission CRF?	No ☐ Yes ☐
At this date (week 5) is this patient in hospital? (this includes if the participant was in hospital following transfer to another site following the initial admission, or any subsequent hospital readmissions)	No ☐ Yes ☐
If yes, was this the initial hospital admission or readmission?	Initial Admission ☐ Readmission ☐

ICU ADMISSIONS	
Please confirm all known ICU admissions within 5 weeks of admission have been recorded on the ICU Admission CRF? *Hyperlink to ICU Admissions form*	No ☐ Yes ☐
If the participant had an ICU admission, was participant in ICU at end of week 5? (this includes if the participant was in ICU following transfer to another site)	No ☐ Yes ☐ NA ☐

ALL HOSPITAL ADMISSIONS WITHIN 5 WEEKS OF ADMISSIONINTO TRIAL

All hospitalisations that occur within 5 weeks of the first admission date must be recorded in the table.
If the participant is transferred to another hospital for continued care this should be treated as a single hospital admission.

Date first admitted to hospital:derived field **5 week date:** derived field

No.	Date admitted to hospital (DD/MMM/YYYY)	Was participant transferred to another hospital following this admission?	If yes, please provide name of hospital where participant was transferred to:	If yes, were they transferred into ICU within 5 weeks of admission?	If participant transferred, date of hospital transfer* (DD/MMM/YYYY)	Date discharged from hospital* (DD/MMM/YYYY)	If not discharged, status: 1 = Died in hospital 2 = Ongoing hospital stay at day 90 3 = Withdrawn consent to follow-up
1	D D M M M 2 0 Y Y	No ☐ Yes ☐		No ☐ Yes ☐	D D M M M 2 0 Y Y	D D M M M 2 0 Y Y	☐
2	D D M M M 2 0 Y Y	No ☐ Yes ☐		No ☐ Yes ☐	D D M M M 2 0 Y Y	D D M M M 2 0 Y Y	☐
3	D D M M M 2 0 Y Y	No ☐ Yes ☐		No ☐ Yes ☐	D D M M M 2 0 Y Y	D D M M M 2 0 Y Y	☐
4	D D M M M 2 0 Y Y	No ☐ Yes ☐		No ☐ Yes ☐	D D M M M 2 0 Y Y	D D M M M 2 0 Y Y	☐
5	D D M M M 2 0 Y Y	No ☐ Yes ☐		No ☐ Yes ☐	D D M M M 2 0 Y Y	D D M M M 2 0 Y	☐

*if participant was transferred to another hospital after admission the participant should be followed-up with that hospital until they are discharged completely from hospital. The date of discharge on the CRF must be the date the participant was discharged completely from hospital.

ALL ADMISSIONS TO INTENSIVE CARE UNIT (ICU) WITHIN 5 WEEKS OF ADMISSION INTO TRIAL

Date first admitted to hospital: derived field

5 week date: derived field

Has participant had an admission to ICU within 5 weeks of the date of hospital admission? No ☐ Yes ☐ Unknown ☐

No.	Admission Date to ICU (DD/MMM/YYYY)	Tick if estimated	Time of Admission (HH:MM) 24HR clock)	Date of discharge from ICU (from this hospital or transferred hospital) (DD/MMM/YYYY)	Tick if estimated	If not discharged, status: 1 = Died in ICU[#] 2 = Still in ICU at day 90 3 = Withdrawn consent to follow-up
1	D D M M M 2 0 Y Y	☐	☐☐ : ☐☐	D D M M M 2 0 Y Y	☐	☐
2	D D M M M 2 0 Y Y	☐	☐☐ : ☐☐	D D M M M 2 0 Y Y	☐	☐
3	D D M M M 2 0 Y Y	☐	☐☐ : ☐☐	D D M M M 2 0 Y Y	☐	☐
4	D D M M M 2 0 Y Y	☐	☐☐ : ☐☐	D D M M M 2 0 Y Y	☐	☐
5	D D M M M 2 0 Y Y	☐	☐☐ : ☐☐	D D M M M 2 0 Y Y	☐	☐

*if participant was transferred to another hospital after admission to ICU the participant should be followed-up with that hospital until they are discharged completely from ICU. The date of discharge on the CRF must be the date the participant was discharged completely from ICU.

[#]Complete death form

DEATH (NCTU or SITE USE)	
Has notification been received the participant has died?	Yes ☐
Date of death	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY Unknown ☐
Time of Death (Only required if within 48 hours of admission)	☐☐ : ☐☐ HH:MM (24 hour clock) Unknown ☐
Source of Death Information	Hospital records ☐ Questionnaire contact (NCTU only) ☐ Other ☐ If Other, specify _____

PROTOCOL DEVIATIONS

Have any protocol deviations taken place? **No** ☐ **Yes** ☐ **Unknown** ☐

No.	Deviation Category (enter code as below)	Date of deviation	Tick if estimated	Comments to describe the deviation
1	☐	D D M M M 2 0 Y Y	☐	
2	☐	D D M M M 2 0 Y Y	☐	
3	☐	D D M M M 2 0 Y Y	☐	
4	☐	D D M M M 2 0 Y Y	☐	
5	☐	D D M M M 2 0 Y Y	☐	
6	☐	D D M M M 2 0 Y Y	☐	
7	☐	D D M M M 2 0 Y Y	☐	
8	☐	D D M M M 2 0 Y Y	☐	
9	☐	D D M M M 2 0 Y Y	☐	
10	☐	D D M M M 2 0 Y Y	☐	

(Record multiple reasons on separate lines) **CODES**

1= Inclusion / Exclusion Criteria Deviation, 2= Study Medication not given as per protocol 3= Other

TRIAL WITHDRAWAL	
Has the participant been withdrawn from the trial?	Yes ☐
If yes, date of withdrawal:	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY
Participant Status: If yes, check the primary reason for Discontinuation *(tick one box):*	Withdrawal of Consent due to Adverse Event ☐ Withdrawal of Consent ☐ Lost to Follow Up ☐ Trial terminated by sponsor ☐ Other ☐ If Other or Withdrawn Consent please specify _____ _____

SIGN OFF STATEMENT

Investigator's Question

To the best of my knowledge, I confirm that I have made every reasonable effort to ensure that ALL of the data in this Case Record Form is a true, accurate and complete report.

Please tick boxes to confirm that the following pages have been completed and their data has ben reviewed:

- ☐ Hospital Admissions
- ☐ ICU Admissions
- ☐ Protocol Deviations

Investigator/designee's Signature: _____ Date D D / M M M / 2 0 Y Y

DD/MMM/YYYY

Participant initials: ☐☐☐	Postal Questionnaire – NCTU use only
Participant Trial ID: ☐☐☐☐☐	

POSTAL QUESTIONNAIRE- 30 DAYS POST HOSPITAL DISCHARGE (NCTU USE ONLY)	
Questionnaire status:	Not required (e.g.participant hospitalised at day 60/died prior to day 60/not sent at participant's request) ☐ Sent ☐
If sent, date sent:	☐☐/☐☐☐/☐☐☐☐ DD/MMM/YYYY

Questionnaire returned?	No ☐ Yes ☐
How many times did the participant consult the GP in the 30 days following discharge from hospital?	☐☐ Unknown ☐
How many times did the participant go back to hospital to seek medical care in the 30 days following discharge from hospital?	☐☐ Unknown ☐
If participant discharged prior to day 5, did the participant complete the treatment course?	Yes ☐ No ☐ Not Applicable ☐

Participant initials: ☐☐☐ **Participant Trial ID:** ☐☐☐☐☐	Participant Completion Status – NCTU use only

PARTICIPANT COMPLETION STATUS (NCTU USE ONLY)	
Please indicate when the participant's data is considered complete	Yes ☐