Screen ID ☐☐☐☐☐ **Date** ☐☐ ☐☐ ☐☐
Day Month Year

ELIGIBILITY CRITERIA

Inclusion Criteria

Patients who meet *all* of the following criteria are eligible for enrolment as study participants:

	Yes	**No**
1. Aged 18 to 60 years on the day of inclusion		
2. Able to provide written informed consent prior to any study procedure		
3. For female participants, must have negative urine pregnancy test at enrollment and willing to take reliable birth control measures for 1 month after vaccination		
4. Able to attend all scheduled visits and to comply with all trial procedures.		

Exclusion Criteria

Patients who meet any of these criteria are not eligible for enrolment as study participants:

	Yes	No
4. Pregnant, lactating women or female who intends to become pregnant during the study period **Urine Pregnancy Test Result:** ☐ **POSITIVE** ☐ Negative		
5. Receipt of any vaccine during the 4 weeks preceding the trial vaccination or planned receipt of any vaccine during the 3 weeks following the trial vaccination		
6. Vaccination against influenza (in a clinical trial or a flu vaccination campaign) or self-reported history of influenza infection (having influenza-like illness) in the past 6 months		
7. Febrile illness (body temperature ≥ 38.0 C) on the day of vaccination (temporary exclusion, a prospective participant should not be included in the study until the febrile event has subsided)		
8. Chronic illness that, in the opinion of the investigator, is at a stage where it might interfere with trial conduct or completion or would increase the risk to the individual by participating in this study		

Form Completed by: _____ Date: _____

Site PI Signature: _____ Date: _____

CRF Assignment by SW

Subject ID ☐☐☐☐☐ **Date** ☐☐ ☐☐ ☐☐
Day Month Year

DEMOGRAPHICS

Date of Informed Consent Form Signed: _____ / _____ / _____ _____ : _____
Day Month Year Hour Min

Year of Birth ☐☐☐☐

Gender: (check one)
- ☐ **Male**
- ☐ **Female**
- ☐ **Unknown or Not Reported**

Ethnicity: (check one)
- ☐ **Hispanic**
- ☐ **Non-Hispanic**
- ☐ **Unknown or Not Reported**

Race: (check all that apply)
- ☐ **American Indian or Alaska Native**
- ☐ **Asian**
- ☐ **Black or African American**
- ☐ **Native Hawaiian or Other Pacific Islander**
- ☐ **White or Caucasian**
- ☐ **Unknown or Not Reported**

VITAL SIGNS

Height ☐☐☐ *in centimetres (cm)*

Weight ☐☐☐ in kilograms (kg)

Blood Pressure (In mmHg) ☐☐☐ / ☐☐☐

Pulse (bpm) ☐☐☐

Body Temperature ☐☐.☐ **ºC**

Respiratory Rate ☐☐ **/min**

Subject ID ☐☐☐☐☐ **Date** ☐☐ ☐☐ ☐☐
Day Month Year

PHYSICAL EXAMINATION

HEENT:	☐ **Normal**	☐ **Abnormal (specify):** _____
CVS:	☐ **Normal**	☐ **Abnormal (specify):** _____
Chest:	☐ **Normal**	☐ **Abnormal (specify):** _____
Abdomen:	☐ **Normal**	☐ **Abnormal (specify):** _____
MSK:	☐ **Normal**	☐ **Abnormal (specify):** _____
Neuro:	☐ **Normal**	☐ **Abnormal (specify):** _____
Other system:	☐ **Normal**	☐ **Abnormal (specify):** _____

DRAWINGS *(only if needed)*

ELIGIBILITY

Is the participant eligible to take part in this study?

☐ **YES**

☐ **NO**

If YES, proceed to the next section.
If NO, end of questionnaire.

QUADRIFLU

Subject ID ☐☐☐☐☐ **Date** ☐☐ ☐☐ ☐☐
Day Month Year

LABORATORY

Date and Time of Sample Collection: _____ / _____ / _____ _____ : _____
Day Month Year Hour Min

Test	Value (Titer unit in Log)
A/H1N1 Antibody Titer	
A/H3N2 Antibody Titer	
B/Yamagata-lineage Antibody Titer	
B/Victoria-lineage Antibody Titer	

VACCINE ADMINISTRATION

Date and Time of Sample Collection: _____ / _____ / _____ _____ : _____
Day Month Year Hour Min

Vaccine Administered By: _____

Vaccination Site:

☐ **Left Arm**

☐ **Right Arm**

☐ **Other (specify):** _____