QUADRIFLU Project: Screening

Study site 0 ☐
01 - Bangkok
02 - Chiang Mai

Screen ID ☐☐☐☐☐

Date ☐☐ Day ☐☐☐ Month ☐☐☐☐ Year

Screening

1. **Sex**
   - ☐ Male
   - ☐ Female

2. **Age** _____ years

3. **Do you have any chronic disease?**
   - ☐ No
   - ☐ Yes (please specify, check all that apply)
     - ☐ High blood pressure
     - ☐ Diabetes mellitus
     - ☐ Heart disease
     - ☐ Immunodeficiency
     - ☐ Lung disease
     - ☐ Gastrointestinal disease
     - ☐ Other……..

4. **Do you have self-reported history of influenza infection in the past 6 months?**
   - ☐ No
   - ☐ Yes

5. **Receipt of vaccine**
   - 5.1. Vaccination against influenza in the past 6 months ☐ No ☐ Yes
   - 5.2. Receipt of any vaccine in the past 4 week ☐ No ☐ Yes
   - 5.3. Plan to receipt of any vaccine during the 3 weeks following the trial ☐ No ☐ Yes

6. **Pregnancy and lactation (for female only)**
   - 6.1. Are you lactating? ☐ No ☐ Yes
   - 6.2. Are you pregnant? ☐ No ☐ Yes

     If yes, what is your urine pregnancy test? (check one only)
     - ☐ Negative
     - ☐ Positive
     - ☐ Not applicable

Form Completed by: _____

QUADRIFLU Project: Enrollment

Study site 0 ☐
01 - Bangkok
02 - Chiang Mai

Random ID ☐☐☐☐☐

Date ☐☐ Day ☐☐☐ Month ☐☐☐☐ Year

Enrollment

Part A: Demographic (check one and/or fill information)

1. **Date of visit (DD MMM YYY)** ☐☐ ☐☐☐ ☐☐☐☐
2. **Date of Informed Consent Form Signed (DD MMM YYY)** ☐☐ ☐☐☐ ☐☐☐☐
3. **Time of informed Consent (24 hours-format, hh:mm)** ☐☐ : ☐☐
4. **Year of birth (YYY)** ☐☐☐☐
5. **Sex** ☐ Male ☐ Female
6. **Race**
   - ☐ Caucasian
   - ☐ Asian
   - ☐ Asian Indians
   - ☐ American Indians
   - ☐ Black or Africa
   - ☐ Hispanic
   - ☐ Other race, please specify: ……..

Part B: Vital sign (fill information)

1. **Weight**_____kilograms
2. **Height** _____ centimeters
3. **Blood pressure**
   - 3.1. **Systolic Blood Pressure** ☐☐☐ mmHg
   - 3.2. **Diastolic Blood Pressure** ☐☐☐ mmHg
   - 3.3. **Pulse Rate** ☐☐☐ beats/min
4. **Respiratory Rate** ☐☐ breaths/min
5. **Body temperature** ☐☐.☐ Celsius

Part C: Physical examination (check one and/or fill information)

Body System	Finding (check one)	Comments (*required if Abnormal)	Clinically Significant* (Yes/No)
HEENT	☐ Normal ☐ Abnormal* ☐ Not examined		
Cardiovascular	☐ Normal ☐ Abnormal* ☐ Not examined		
Chest	☐ Normal ☐ Abnormal* ☐ Not examined		
Abdomen	☐ Normal ☐ Abnormal* ☐ Not examined		
Musculoskeletal	☐ Normal ☐ Abnormal* ☐ Not examined		
Neurological	☐ Normal ☐ Abnormal* ☐ Not examined		
Other Body System:……..	☐ Normal ☐ Abnormal* ☐ Not examined		

Part D: Eligible check

1. **Inclusion Criteria:** Patients who meet all of the following criteria are eligible for enrollment as study participants

Inclusion criteria	Yes	No
1. Male or Female		
2. Age 18 to 60 years		
3. Able to provide written informed consent		
4. For female – negative urine pregnancy test result at enrollment		
5. Able to attend all scheduled visits and comply with all procedures		

2. **Exclusion Criteria:** Patients who meet any of these criteria are not eligible for enrollment as study participants

Exclusion criteria	Yes	No
6. Pregnant, lactating women or female who intends to become pregnant during the study		
7. Receipt of any vaccine in the past 4 week or plan to receipt of any vaccine during the 3 weeks following the trial		
8. Vaccination against influenza in the past 6 months or history of influenza infection in the past 6 months		
9. Febrile illness (body temperature 38 Celsius or more)		
10. Chronic disease that would increase the risk of participant		

3. **Summary: Is the participant eligible to take part in this study?**
   - ☐ Yes
   - ☐ No

Part E: Laboratory (fill information)

1. **Date of Sample Collection (DD MMM YYY)** ☐☐ ☐☐☐ ☐☐☐☐
2. **Time of Sample Collection (24 hours-format, hh:mm)** ☐☐ : ☐☐
3. **Antibodies titers**
   - **3.1.** A/H1N1 Antibody Titer ☐ : ☐☐☐☐
   - **3.2.** A/H3N2 Antibody Titer ☐ : ☐☐☐☐
   - **3.3.** B/Yamagata-lineage Antibody Titer ☐ : ☐☐☐☐
   - **3.4.** B/Victoria-lineage Antibody Titer ☐ : ☐☐☐☐

Part F: Vaccine administration (check one and/or fill information)

1. **Date of Vaccination (DD MMM YYY)** ☐☐ ☐☐☐ ☐☐☐☐
2. **Time of Vaccination (24 hours-format, hh:mm)** ☐☐ : ☐☐
3. **Vaccination Arm** ☐ Left ☐ Right