Protocol title: QUADRIFLU Clinical Research Form

Screening Form (1/2)

Screen ID: ☐ ☐☐☐ ☐

Site Subject No. Initial

Eligibility Criteria

Age: ☐☐ years

Please mark ✓ at the appropriate box	
Pregnant?	☐ Yes ☐ No ☐ No Data
Lactating?	☐ Yes ☐ No ☐ No Data
Plan to become pregnant during this month?	☐ Yes ☐ No ☐ No Data
Receipt of any vaccine during the 4 weeks preceding the trial?	☐ Yes ☐ No ☐ No Data
Plan to receive any vaccine during the 3 weeks following the trial?	☐ Yes ☐ No ☐ No Data
Vaccination against influenza in the past 6 months?	☐ Yes ☐ No ☐ No Data
Self-reported history of influenza infection in the past 6 months?	☐ Yes ☐ No ☐ No Data
Does the subject have a chronic disease?	☐ Yes ☐ No ☐ No Data if "Yes" please mark ✓ at the group of disease and specify ☐ HEENT: ..... ☐ Respiratory: ..... ☐ Cardiovascular: ..... ☐ Gastrointestinal/Hepatic: ..... ☐ Genitourinary: ..... ☐ Musculoskeletal: ..... ☐ Neurological: ..... ☐ Endocrine-Metabolic: ..... ☐ Hematologic/Lymphatic: ..... ☐ Dermatologic: ..... ☐ Psychiatric: ..... ☐ Other: .....

Completed by: ..... Date completed: ☐☐ ☐☐ 20☐☐

Day Month Year

Screening Form (2/2)

Screen ID: ☐ ☐☐☐ ☐

Site Subject No. Initial

Eligibility Criteria (Continued)

Does the subject have history of allergies?	☐ Yes ☐ No ☐ No Data if "Yes" please mark ✓ at the allergic group and specify ☐ Medicine: ..... ☐ Food: ..... ☐ Other: .....

Laboratory Test

Please mark ✓ at the appropriate box	
Urine pregnancy test	Results: ☐ Pregnant ☐ None pregnant ☐ No Data

Completed by: ..... Date completed: ☐☐ ☐☐ 20☐☐

Day Month Year

Protocol title: QUADRIFLU Clinical Research Form

Enrollment Form (1/4)

Random ID: ☐ ☐☐☐ ☐

Site Subject No. Initial

Demographic

Date of visit: ☐☐ ☐☐ 2 0 ☐☐

Day Month Year

Year of Birth (Christian Year): ☐☐☐☐

Gender: ☐ Female ☐ Male

Race:
- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African-American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ More than one race
- ☐ Unknown or not reported

Inform Consent

Please mark ✓ at the appropriate box

Waiver of consent granted for recruitment purposes? ☐ Yes ☐ No

if "Yes" please provide the information below

Date of Informed Consent Form Signed: ☐☐ ☐☐ 2 0 ☐☐

Day Month Year

Time of informed Consent: ☐☐:☐☐

hh mm

Completed by: _____ Date completed: ☐☐ ☐☐ 2 0 ☐☐

Day Month Year

Protocol title: QUADRIFLU Clinical Research Form

Enrollment Form (2/4)

Random ID: ☐ ☐☐☐ ☐

Site Subject No. Initial

Vital Signs

Height ☐☐☐.☐ cm	Weight ☐☐☐.☐ kg	Temperature ☐☐.☐ °c
Blood Pressure Systolic Diastolic ☐☐☐ / ☐☐☐ mmHg	Pulse Rate ☐☐☐ bpm	Respiratory Rate ☐☐☐ bpm

Physical Exam

Please mark ✓ at the appropriate box ☐

☐ Please check if **all** not done

Category	Normal	Abnormal	If Abnormal please specify	Not Done
HEENT	☐	☐		☐
Cardiovascular	☐	☐		☐
Chest	☐	☐		☐
Abdomen	☐	☐		☐
Musculoskeletal	☐	☐		☐
Neurological	☐	☐		☐
Other	☐	☐		☐

Completed by: ..... Date completed: ☐☐ ☐☐ 20☐☐

Day Month Year

Protocol title: QUADRIFLU Clinical Research Form

Enrollment Form (3/4)

Random ID: ☐ ☐☐☐ ☐

Site Subject No. Initial

Eligibility Check

Is this participant eligible to take part in this study?

☐ Yes ☐ No

if "No" please mark ✓ at the none eligible reason

☐ Age
☐ Pregnant or plan for pregnant or lactating
☐ Receipt of any vaccine during the 4 weeks preceding the trial
☐ Plan to receipt of any vaccine during the 3 weeks following the trial
☐ Vaccination against influenza in the past 6 month
☐ Self-reported history of influenza infection in the past 6 months
☐ Febrile illness (body temperature ≥ 38 ◦c)
☐ Chronic illness:----------
☐ Other:----------

Laboratory

Please mark ✓ at the appropriate box ☐

☐ Please check if **all** not done

Is the date of Sample collection the same as Date of Visit?

☐ Yes ☐ No, specify: ☐☐ ☐☐ 2 0 ☐☐

Day Month Year

Time of sample collection: ☐☐:☐☐

hh mm

Test	Result	Unit	Undetectable	Not Done
A/H1N1 Antibody Titer		IU/mL	☐	☐
A/H3N2 Antibody Titer		IU/mL	☐	☐
B/Yamagata-lineage Antibody Titer		IU/mL	☐	☐
B/Victoria-lineage Antibody Titer		IU/mL	☐	☐

Completed by: ---------- Date completed: ☐☐ ☐☐ 2 0 ☐☐

Day Month Year

Enrollment Form (4/4)

Random ID: ☐ ☐☐☐ ☐

Site Subject No. Initial

Vaccine Administration

please mark ✓ at the appropiate box ☐

Is the date of Vaccination the same as Date of Visit?

☐ Yes ☐ No, specify: ☐☐ ☐☐ 2 0 ☐☐

Day Month Year

Time of Vaccination: ☐☐:☐☐

hh mm

Vaccination Arm: ☐ Left ☐ Right

Completed by: ..... Date completed: ☐☐ ☐☐ 2 0 ☐☐

Day Month Year