Screening Visit (Day 0)

Demographics

All dates are entered in the MM-DD-YYYY format. Insert 2 numbers for the month (MM), 2 numbers for the day (DD) and the year in Christian using 4 digits.

Site Number: ☐☐	Subject ID: ☐☐☐☐☐	Visit Date (mm/dd/yyyy): ☐☐/☐☐/☐☐☐☐
Study Visit: ☐Screening ☐Enrollment ☐Follow-up ☐Unscheduled		

Gender: ☐Female ☐Male

Date of Birth (mm/dd/yyyy)**:** ☐☐/☐☐/☐☐☐☐

Race (Select ONLY one with which you MOST CLOSELY identify):

- ☐ 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

Ethnicity (Select ONLY one with which you MOST CLOSELY identify):

- ☐ Thai
- ☐ Myanmar
- ☐ Cambodia
- ☐ Laos
- ☐ Chinese
- ☐ Vietnam
- ☐ Unknown or not reported

Does the subject have a medical history, current or resolved, of any of the following?

Medical History	Yes/No	UNK unknown	If yes, describe (include onset date mm/dd/yyyy)	Current/Resolved
Respiratory	☐ Yes ☐ No	☐	_____ ☐☐/☐☐/☐☐☐☐	☐ Current ☐ Resolved
Cardiovascular	☐ Yes ☐ No	☐	_____ ☐☐/☐☐/☐☐☐☐	☐ Current ☐ Resolved
Neurological	☐ Yes ☐ No	☐	_____ ☐☐/☐☐/☐☐☐☐	☐ Current ☐ Resolved
Gastrointestinal	☐ Yes ☐ No	☐	_____ ☐☐/☐☐/☐☐☐☐	☐ Current ☐ Resolved
Endocrine-Metabolic	☐ Yes ☐ No	☐	_____ ☐☐/☐☐/☐☐☐☐	☐ Current ☐ Resolved
Allergy	☐ Yes ☐ No	☐	_____ ☐☐/☐☐/☐☐☐☐	☐ Current ☐ Resolved
Influenza infection history	☐ Yes ☐ No	☐	_____ ☐☐/☐☐/☐☐☐☐	☐ Current ☐ Resolved

Vital Signs

All times use the 24 hour clock. (e.g. 13:00 and not 1:00 PM), Midnight is 00:00 with the next day's date.

Time ____:____

Height _____ ☐ inches ☐ centimeters ☐ not done.

Weight _____ ☐ pounds ☐ kilograms ☐ not done.

BMI _____ kg/m2

Heartrate _____ bpm

Blood pressure ____/_____ (systolic/diastolic) ☐ not done.

BP position ☐ sitting ☐ supine ☐ standing

Temperature _____ ☐ °C ☐ °F ☐ not done.

Source ☐ oral ☐ tympanic ☐ other

Respiratory Rate _____ /min

Eligibility Criteria

Able to attend all scheduled visits and comply with all trial procedures ☐ Yes ☐ No

Positive Pregnancy test result (for female participants): ☐ Negative ☐ Positive

Intends to become pregnant during the study period ☐ Yes ☐ No

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

☐ Yes ☐ No

Vaccination against influenza (in a clinical trial or a flu vaccination campaign) in the past 6 months.

☐ Yes ☐ No

Informed Consent Process

☐ Waiver of consent granted for recruitment purposes

☐ Informed Consent Signed (mm/dd/yyyy): ☐☐/☐☐/☐☐☐☐

Completed by (initials) :	Date completed(mm/dd/yyyy): ☐☐/☐☐/☐☐☐☐

Enrollment Visit (Day 0)

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Site Number: ☐☐	Subject ID: ☐☐☐☐☐	Visit Date (mm/dd/yyyy): ☐☐/☐☐/☐☐☐☐
Study Visit: ☐Screening	☐Enrollment	☐Follow-up ☐Unscheduled

Study Drug/Vaccine Administration

Vaccine type: ☐ Quadrivalent influenza vaccine (QIV)

☐ Trivalent influenza vaccine (TIV)

Dose: 0.5 mL

Route: Intramuscular

Site: ☐ Left deltoid ☐ Right deltoid

Lot number: ☐☐☐☐☐☐☐☐

Expiry date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yy)

Post Injection Reaction

Pain at injection site: ☐ None ☐ Mild ☐ Moderate ☐ Severe

Redness at injection site: ☐ None ☐ Mild (< 2.5 cm) ☐ Moderate (2.5 - 5 cm)

☐ Severe (> 5 cm)

Swelling at injection site: ☐ None ☐ Mild (< 2.5 cm) ☐ Moderate (2.5 - 5 cm) ☐ Severe (> 5 cm)

Induration at injection site: ☐ None ☐ Mild (< 2.5 cm) ☐ Moderate (2.5 - 5 cm) ☐ Severe (> 5 cm)

Ecchymosis at injection site: ☐ None ☐ Mild (< 2.5 cm) ☐ Moderate (2.5 - 5 cm) ☐ Severe (> 5 cm)

Laboratory Results

HAI titers for influenza antigens at baseline:

A/H1N1pdm09 strain: _____

A/H3N2 strain: _____

B/Victoria lineage strain: _____

B/Yamagata lineage strain (for QIV only): _____

Diary Card Distribution

Diary card number: ☐☐☐☐☐☐☐☐

Instructions for recording solicited and unsolicited adverse events:

- Record any local or systemic reaction that occurs within 7 days after vaccination on the diary card.
- Record any adverse event, including serious adverse event, that occurs within 21 days after vaccination on the diary card.
- Contact the study site if you have any questions or concerns about the diary card or the adverse events.