| **Screening Number:** ☐☐☐☐ | **ELIGIBILITY CRITERIA** | **SCREENIG VISIT** |
|---|---|---|

**Date of Visit:** ☐☐/☐☐☐/☐☐☐☐
DD MMM YYYY

| **INCLUSION CRITERIA**<br>*(A volunteer will be eligible for inclusion if ALL the following criteria are met at the time of screening)* | **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**<br>*(Volunteers with ANY of the following criteria at screening will not be eligible for participation)* | **Yes** | **No** |
| 1. Pregnant, lactating women or female who intends to become pregnant during the study period | ◯ | ◯ |
| 2. 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 | ◯ | ◯ |
| 3. 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 | ◯ | ◯ |
| 4. 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) | ◯ | ◯ |
| 5. 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 | ◯ | ◯ |
| **PREGNANCY TEST** | ☐ Pos ☐ Neg<br>☐ ND ☐ NA | |
| **ELIGIBILITY SUMARY** | | |
| 1. Does the participant meet all of the inclusion criteria? | ◯ | ◯ |
| 2. Does the participant meet the exclusion criteria? | ◯ | ◯ |
| 3. Is participant eligible for the study | ◯ | ◯ |
| 4. Date Consent Form Signed ☐☐/☐☐☐/☐☐☐☐<br>DD MMM YYYY | | |
| 5. Is copy of study informed consent offered to participant? | ◯ | ◯ |
| **RESEARCH STAFF SIGN-OFF FOR PARTICIPANT ELIGIBILITY** | | |
| Research Staff's Signature<br><br>Research Staff's Name<br><br>Date signed: ☐☐/☐☐☐/☐☐☐☐<br>DD MMM YYYY | | |

| **Screening Number:** ☐☐☐☐ | **Site Number- Participant Number:** ☐☐-☐☐☐☐ | **ENROLLMENT VISIT** |
|---|---|---|

**Date of Visit:** ☐☐/☐☐☐/☐☐☐☐
DD MMM YYYY

## DEMOGRAPHICS

**Date of Birth:** ☐☐/☐☐☐/☐☐☐☐
DD MMM YYYY

**Age:** ☐☐☐ Years **Sex:** ☐ Male ☐ Female ☐ 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

## PHYSICAL EXAMINATION:

**Hight (cm.)** ☐☐☐.☐ ☐ **NA** **Weight (kg.)** ☐☐☐.☐
***(Enrollment visit only)*** ***(check this box if other Visit)***

## VITAL SIGNS:

**Time:** ☐☐:☐☐ *(using 24 hour format of hh:mm)*

**Body Temperature:** ☐☐.☐ **°C** **Heart Rate:** ☐☐☐ bpm

**Blood Pressure: Systolic** ☐☐☐ mmHg **Diastolic** ☐☐☐ mmHg

**Respiratory rate:** ☐☐☐ bpm

Record clinically significant physical findings by checking 'Normal, 'Abnormal' or 'Not done' for each body system. If 'Abnormal' record finding(s) in the 'If Abnormal, describe' column. Otherwise, leave this column blank

| **Body system** | **Record Physical Examination Findings** | | | **If Abnormal, describe** |
|---|---|---|---|---|
| | **Normal** | **Abnormal** | **Not done** | |
| HEENT | ☐ | ☐ | ☐ | |
| Cardiovascular | ☐ | ☐ | ☐ | |
| Chest | ☐ | ☐ | ☐ | |
| Abdomen | ☐ | ☐ | ☐ | |
| Musculoskeletal | ☐ | ☐ | ☐ | |
| Neurological | ☐ | ☐ | ☐ | |
| Other body systems | ☐ | ☐ | ☐ | |

** If there are no findings for the 'Other' category, leave the status for this column blank*

Research Staff's Signature Research Staff's Name

Date signed: ☐☐/☐☐☐/☐☐☐☐
DD MMM YYYY

| **Screening Number:** ☐☐☐☐ | **Site Number- Participant Number:** ☐☐-☐☐☐☐ | **ENROLLMENT VISIT** |
|---|---|---|

**Date of Visit:** ☐☐/☐☐☐/☐☐☐☐ (Same as Enrollment Visit) ☐
DD MMM YYYY

## VACCINATION

1. Is the participant eligible to take part in this study? (Eligibility check): ☐ Yes ☐ No
2. Vaccination Arm:

☐ Quadrivalent influenza vaccine (QIV)
☐ Trivalent influenza vaccine (TIV)

3. Dose administered time ☐☐:☐☐ *(using 24 hour format of hh:mm)*

## LABORATORY TEST

**Date of Sample collection:** ☐☐/☐☐☐/☐☐☐☐
DD MMM YYYY

**Time of sample collection:** ☐☐:☐☐ *(using 24 hour format of hh:mm)*

1. A/H1N1 Antibody titer: ☐ Non-reactive ☐ Titer 1:☐☐☐☐
2. A/H3N2 Antibody titer: ☐ Non-reactive ☐ Titer 1:☐☐☐☐
3. B/Yamagata Antibody titer: ☐ Non-reactive ☐ Titer 1:☐☐☐☐
4. Note Done: ☐

Research Staff's Signature Research Staff's Name

Date signed: ☐☐/☐☐☐/☐☐☐☐
DD MMM YYYY

| Site Number- Participant Number: ☐☐-☐☐☐☐ | VISIT: Enrollment ☐ : Unscheduled ☐ |
|---|---|

**Date of Visit:** ☐☐/☐☐☐/☐☐☐☐ (Same as Enrollment Visit) ☐
DD MMM YYYY

## SOLICITED SYMPTOMS

**Does subject have any symptoms listed in the table below?**

☐ **Yes** *(complete below)* ☐ **No** *(CRF is complete)*

Check one status for each symptom in the table below. Do not leave any symptom status blank. If symptom is not present, check 'None'.

For any symptoms present, record as an Adverse Event on the AE CRF. In table below, cross reference the AE page term which records the symptoms. Note: more than one symptom may be included in the same AE term if a syndrome name is recorded as the AE term

| Symptom | Check one status for symptom | | | | If 'Mild', 'Moderate' or 'Severe', record AE term recorded on AE page |
|---|---|---|---|---|---|
| | None (0) | Mind (1) | Moderate (2) | Severe (3) | |
| **Pain** | | | | | |
| **Readness** | | | | | |
| **Malaise** | | | | | |
| **Swelling** | | | | | |
| **Induration** | | | | | |
| **Ecchymosis** | | | | | |
| **Headache** | | | | | |
| **Shivering** | | | | | |
| **Fever** | | | | | |

Research Staff's Signature Research Staff's Name

Date signed: ☐☐/☐☐☐/☐☐☐☐
DD MMM YYYY