| STUDY<br>STUDYID | | SUBJECTID<br>USUBJID | | SITE<br>SITEID | |
|---|---|---|---|---|---|

| VISIT 1 | VISIT DATE | \|_\|_\|-\|_\|_\|_\|-\|_\|_\|_\|_\|<br>VISDAT<br><br>Record the start date using this format (DD-MON-YYYY). | VISIT TIME | \|_\|_\|:\|_\|_\|<br>VISTIM<br>(using 24 hour format) |
|---|---|---|---|---|

## ELIGIBILITY ASSESSMENT

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

| Inclusion Criteria | Criterion Description | Yes | No |
|---|---|---|---|
| 1. | Subject between the age of 18 and 60 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 | | |

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

| Exclusion Criteria | Criterion Description | 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. | | |

## INFORM CONSENT

| | | | |
|---|---|---|---|
| **Date Signed** | \|_\|_\|-\|_\|_\|_\|-\|_\|_\|_\|_\| | **Time Signed** (using 24 hour format) | \|_\|_\|:\|_\|_\| |

| Document(s) Signed | Version Date | Approval Date |
|---|---|---|
| | | |
| | | |
| | | |

| Consent | Yes | No |
|---|---|---|
| Consent Form, and related study documents, was thoroughly reviewed with the subject. | | |
| Subject had sufficient time to review the documents and ask questions. | | |
| Informed consent/HIPAA Authorization obtained prior to any study related procedures. | | |
| A copy of the signed documents have been given to the subject. | | |

| | |
|---|---|
| Name of person that obtained consent | |
| Comments | |

## MEDICAL HISTORY

| Body System | Diagnosed condition? | Diagnosis/Condition/Surgery | Onset Date or Year | Current Problem |
|---|---|---|---|---|
| HIV Status | ☐ Yes<br>☐ No | | | ☐ Yes<br>☐ No |
| Hepatitis B or C | ☐ Yes<br>☐ No | | | ☐ Yes<br>☐ No |
| hypersensitivity to any of the vaccine components or history of a life-threatening reaction to the vaccine used in the study or to a vaccine containing any of the same substances | ☐ Yes<br>☐ No | | | ☐ Yes<br>☐ No |
| known or suspected thrombocytopenia | ☐ Yes<br>☐ No | | | ☐ Yes<br>☐ No |
| bleeding disorder or receipt of anticoagulants in | ☐ Yes<br>☐ No | | | ☐ Yes<br>☐ No |

| | | | | |
|---|---|---|---|---|
| the 3 weeks preceding inclusion; alcohol abuse or drug addiction | | | | |
| chronic illness that was at a stage where it might interfere with trial conduct or completion | ☐ Yes<br>☐ No | | | ☐ Yes<br>☐ No |
| moderate or severe acute illness or infection on the day of vaccination | ☐ Yes<br>☐ No | | | ☐ Yes<br>☐ No |

## VITAL SIGN

| | | | |
|---|---|---|---|
| **Date Measurement** | \|_\|_\|-\|_\|_\|_\|-\|_\|_\|_\|_\| | **Time Measurement** (using 24 hour format) | \|_\|_\|:\|_\|_\| |

| | | | |
|---|---|---|---|
| **Height** | _____<br>In Centimeters<br><br>☐ *Height not measured* | **Weight** | _____<br>In Kg<br><br>☐ Weight *not measured* |

| | | |
|---|---|---|
| Temperature | _____ Celcius<br><br>**Method:** (check one)<br>☐ Oral ☐ Axillary ☐ Tympanic | ☐ *Temperature not measured* |
| Respiratory Rate | _____ breath/min | ☐ *Respiratory Rate not measured* |
| Heart Rate | _____ beaths/min | ☐ *Heart Rate not measured* |
| | | |

| | | |
|---|---|---|
| Systolic Blood Pressure | _____ mmHg | ☐ *Blood Pressure not measured* |
| Diastolic Blood Pressure | _____ mmHg<br><br>Method: (check one)<br>☐ Manual ☐ Automated<br><br>Location: (check one)<br>☐ Left Arm ☐ Right Arm<br><br>Position: (check one)<br>☐ Sitting ☐ Supine ☐ Standing | |

Additional Notes:
_____

Vital Sign Measurements obtained by: _____

## PHYSICAL EXAMINATION

| | | | |
|---|---|---|---|
| **Date Measurement** | __-__-____ | **Time Measurement** (using 24 hour format) | __:__ |

| Body System | Finding (Check one) | Comments (required if abnormal) | Clinically Significant (Yes/No) |
|---|---|---|---|
| **Heart rate** | ☐ Normal<br>☐ Abnormal*<br>☐ Not examined | | |
| **Pulse** | ☐ Normal<br>☐ Abnormal*<br>☐ Not examined | | |
| **Tap Stomach** | ☐ Normal<br>☐ Abnormal*<br>☐ Not examined | | |
| **Check eyes and tongue** | ☐ Normal<br>☐ Abnormal*<br>☐ Not examined | | |

## VACCINATION

| | | | |
|---|---|---|---|
| **Date of Vaccination** | \|_\|_\|-\|_\|_\|_\|-\|_\|_\|_\|_\| | **Time of Vaccination** (using 24 hour format) | \|_\|_\|:\|_\|_\| |

## Group of Vaccine

☐ QIV Vaccine
☐ TIV Vaccine

Vital Sign Vaccination obtained by: _____