# Inclusion/Exclusion

## Inclusion

Subject Number _____

Subject Initials _____

Has subject met all inclusion and exclusion criteria?
☐ No
☐ Yes

1. Has the subject given written informed consent?
☐ No
☐ Yes

2. Is the subject in good health?
☐ No
☐ Yes

3. Is the subject between the ages of 50 and 74 years?
☐ No
☐ Yes

4. Is the subject able to follow study procedures?
☐ No
☐ Yes

5. Is the subject expected to be available for the duration of the study?
☐ No
☐ Yes

6. Does the subject agree NOT to donate blood during the length of the study or in the 56 days after the last blood draw?
☐ No
☐ Yes

7. If the subject has any medical conditions, are those conditions stableâ€"where stable is defined as not requiring either a significant change in therapy or a hospitalization in the last 12 weeks?
☐ No
☐ Yes

## Exclusion

8. Has the subject received this yearâ€™s 2010-2011 influenza vaccine outside of this study?
☐ No
☐ Yes

9. Has the subject had a severe reaction that was associated with the influenza vaccine?
☐ No
☐ Yes

10. Is the subject allergic to egg proteins (egg or egg products)?
☐ No
☐ Yes

11. Does the subject have a history of Guillian-Barre syndrome?
☐ No
☐ Yes

12. Does the subject have trouble with blood draws?
☐ No
☐ Yes

13. Does the subject have a known or suspected immunodeficiency or receiving treatment with immunosuppressive therapy including cytotoxic agents or systemic corticosteroids (eg, for cancer, HIV, or autoimmune disease?
☐ No
☐ Yes

| | |
|---|---|
| 14. Has the subject received systemic corticosteroids for treatment of an acute illness in the last 30 days? | ☐ No<br>☐ Yes |
| 15.Does the subject have a serious chronic disorder including metastatic malignancy, severe chronic obstructive pulmonary disease requiring supplemental oxygen, end stage renal disease with or without dialysis, clinically unstable cardiac disease, or any other disorder that in the investigators opinion precludes the subject from participating in the study? | ☐ No<br>☐ Yes |
| 16.Has the subject received any blood products, including immunoglobulin, within 6 months of study enrollment? | ☐ No<br>☐ Yes |
| 17. Is the subject receiving anticoagulant therapy or have a history of bleeding diathesis that would contraindicate intramuscular (IM) injection? Note: antiplatelet drugs such as aspirin and clopidogrel are permitted. | ☐ No<br>☐ Yes |
| 18. Does the subject intend to receive any other investigational vaccine or agent during the course of the study? | ☐ No<br>☐ Yes |
| 19. If the flu season has begun, has subject been diagnosed with the flu or flu like illness or had flu-like symptoms this season? | ☐ No<br>☐ Yes |
| 20. Does the subject have any medical condition that would, in the opinion of the investigator, interfere with the evaluation of the study objectives? | ☐ No<br>☐ Yes |
| 21. Has the subject donated blood with in the last 58 days? | ☐ No<br>☐ Yes |
| 22. Does the subject have a known allergy to latex? | ☐ No<br>☐ Yes |

# Consent/Demographics

## Inclusion

Subject Number _____

## Visit Location

Location

- ☐ CRU
- ☐ Gonda 10
- ☐ Other

## INFORMED CONSENT

Has the informed consent been reviewed with the subject/legal guardian and all questions answered, and all required signatures obtained?

- ☐ No
- ☐ Yes

Date Informed Consent was signed: _____

Was consent signed before any study procedures performed ?

- ☐ No
- ☐ Yes

## DEMOGRAPHICS

Date of Birth _____

Gender

- ☐ Male
- ☐ Female

Ethnic Origin:

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown

Race:

- ☐ American Indian/Alaska Native
- ☐ Asian
- ☐ Native Hawaiian or other Pacific Islander
- ☐ Black or African American
- ☐ White
- ☐ More than one race
- ☐ Unknown

Did subject meet all study entry criteria specified in the protocol?

- ☐ No
- ☐ Yes

# Blood/Vac-Day 0

## Inclusion

Subject Number _____

## Blood Samples

Was blood sample obtained from the subject?
- ☐ No
- ☐ Yes

Net Weight of blood drawn _____ (g)

Label ID _____

Initials of Staff _____

## Vaccination

Date of Vaccination: _____

Lot # of vaccine
- ☐ AFLUA524AA
- ☐ Other

Specify other Lot # _____

Site of Vaccination:
- ☐ Left Deltoid
- ☐ Right Deltoid