Week 2 Assignment 1 : CRF Design

According to the “QUADRIFLU” project, you have designed the data including visits, domains, and variables to be collected in the study. ***Please design a Case Record Form (CRF) only for “Screening” and “Enrollment” visits*** according to domains and variables defined in the first week. (Here is revised version of variables part screening and enrollment)

Visits	Domain	Variables
Screening	Identifier	• ScreenID • Site No • Initials • Date of screening
	Eligibility Criteria	• Age • Pregnant or lactating • Receive any vaccine within 4 weeks preceding the trial • Plan to receive vaccine during 3 weeks following the trial • Received influenza vaccine in the past 6 months • Had influenza illness in the past 6 months • Chronic illness • History of anaphylactic reaction to previous influenza vaccine • History of Guillain-Barre' syndrome (GBS) within 6 weeks after previous dose of influenza vaccine • Current medication of immunosuppressive agents • Bleeding disorders or current anticoagulant/antiplatelet drug use
	Laboratory	• Pregnancy test
	Screening Criteria	• Does participant meet the criteria for study
Enrollment VISIT1(day0)	Identifier	• Random ID
	Demographics	• Date of visit • Date of informed Consent Form Signed • Time of informed consent form signed • Year of Birth • Sex (biologically determined) • Race/ethnicity
	Vital signs	• Height (cm) • Weight (kg) • *BMI (calculated)* • Blood pressure (mmHg) • Heart rate (bpm), • Respiratory rate (breath/min) • Body Temperature (^{o}C)
	Physical Examination	• HEENT • CVS • Chest • Abdomen • MSK • Neurological • Review of other system
	Eligible check	• Is participant eligible to take part in the study
	Laboratory	• Date of sample collection • Time of sample collection

		• A/H1N1 Antibody titer • A/H3N1 Antibody Titer • B/Yamagata-lineage Antibody Titer • B/Victoria-lineage Antibody Titer
	Vaccine administration	• Date of Vaccination • Time of vaccination • Type of vaccine received ; QIV, TIV

S101: Immunogenicity and Safety of a Quadrivalent Influenza Vaccine Given Intramuscularly in Participants Aged 18 to 60 Years				
CRF01	Screening Form			
Site No. ☐	Screening ID ☐☐☐	Initials ☐☐	Date of Screening ☐☐ *day* ☐☐ *month* ☐☐☐☐ *year*	
Eligible Criteria				
1	Aged between 18 and 60 years old on the day of screening	☐ Yes	☐$_0$ No	
2	Able to provide written informed consent prior to any study procedure	☐ Yes	☐$_0$ No	
3	Pregnancy *(for male, please check "NA")*	☐$_0$ Yes	☐ No	☐ NA
4	Willing to take reliable birth control measures for 1 month after vaccination *(for male, please check "NA")*	☐ Yes	☐$_0$ No	☐ NA
5	Lactating *(for male, please check "NA")*	☐$_0$ Yes	☐ No	☐ NA
6	Receive any vaccine within 4 weeks preceding the trial	☐$_0$ Yes	☐ No	
7	Plan to receive vaccine during 3 weeks following the trial	☐$_0$ Yes	☐ No	
8	Vaccination against influenza in the past 6 months	☐$_0$ Yes	☐ No	
9	Self-reported history of influenza infection in the past 6 months	☐$_0$ Yes	☐ No	
10	Chronic illness that might interfere with the trial or increase participant risk	☐$_0$ Yes	☐ No	
11	History of anaphylactic reaction to previous influenza vaccine	☐$_0$ Yes	☐ No	
12	History of Guillain-Barre' syndrome (GBS) within 6 weeks after previous dose of influenza vaccine	☐$_0$ Yes	☐ No	
13	Current medication of immunosuppressive agents	☐ Yes	☐ No	
14	Bleeding disorders or current anticoagulant/antiplatelet drug use	☐ Yes	☐ No	
15	Able to attend all scheduled visits and comply with all procedures	☐ Yes	☐$_0$ No	
Laboratory				
16	Urine Pregnancy test *(for male, please check "NA")*	☐$_0$ Positive	☐ Negative	☐ NA
Screening Result				
17	Is participant eligible for criteria (*Check No, if any checkbox* ☐$_0$ in this form)	☐ Yes	☐ No	
18	Assigned Random ID	☐☐☐		

S101: Immunogenicity and Safety of a Quadrivalent Influenza Vaccine Given Intramuscularly in Participants Aged 18 to 60 Years			
CRF02	Enrollment Form		
Site No. ☐	Random ID. ☐☐☐	Initials ☐☐	Date of visit ☐☐ (day) ☐☐ (month) ☐☐☐☐ (year)
Demographic			
1	Informed Consent	Date of Informed Consent Form Signed ☐☐ (day) ☐☐ (month) ☐☐☐☐ (year)	Time of Informed Consent Form Signed *(24-hr Format)* ☐☐ (hour) : ☐☐ (minute)
2	Year of Birth	☐☐☐☐	
3	Sex (biologically determined)	☐ Male ☐ Female	
4	Race	☐ Asian ☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Black or African American ☐ Tribe ☐ Other, specify	
Vital Signs			
5	Height	☐☐☐ . ☐ cm	
6	Weight	☐☐☐ . ☐ kg	
7	Blood pressure	Systolic ☐☐☐ mmHg	Diastolic ☐☐ mmHg
8	Pulse Rate	☐☐☐ beats per minute	
9	Respiratory rate	☐☐ times per minute	
10	Body Temperature	☐☐ . ☐ °C	
Physical Examination			
11	HEENT	☐ Normal ☐ Abnormal, specify	
12	Cardiovascular	☐ Normal ☐ Abnormal, specify	
13	Chest	☐ Normal ☐ Abnormal, specify	
14	Abdomen	☐ Normal ☐ Abnormal, specify	

15	Musculoskeletal	☐ Normal	☐ Abnormal, specify ……
16	Neurological	☐ Normal	☐ Abnormal, specify ……
17	Review of other Body system	☐ Normal	☐ Abnormal, specify ……
Eligible Check			
18	Is the participant eligible to take part in this study	☐ Yes	☐ No
Laboratory			
19	Laboratory	Date of Sample Collection ☐☐ ☐☐ ☐☐☐☐ *day* *month* *year*	Time of Sample Collection *(24-hr Format)* ☐☐ : ☐☐ *hour* *minute*
20	A/H1N1 Antibody Titer	☐☐☐ . ☐☐	
21	A/H3N1 Antibody Titer	☐☐☐ . ☐☐	
22	B/Yamagata-lineage Antibody Titer	☐☐☐ . ☐☐	
23	B/Victoria-lineage Antibody Titier	☐☐☐ . ☐☐	
Vaccine Administration			
24	Vaccination	Date of vaccination ☐☐ ☐☐ ☐☐☐☐ *day* *month* *year*	Time of vaccination *(24-hr Format)* ☐☐ : ☐☐ *hour* *minute*
25	Vaccination Arm	☐ QIV	☐ TIV

Note: After I uploaded the assignment in pdf, the check box symbol didn't show up in the form, so I re-upload again in word document and add another page of CRF in picture just in case.

S101: Immunogenicity and Safety of a Quadrivalent Influenza Vaccine Given Intramuscularly in Participants Aged 18 to 60 Years				
CRF01	Screening Form			
Site No. ☐	Screening ID ☐☐☐	Initials ☐☐	Date of Screening ☐☐ (day) ☐☐ (month) ☐☐☐☐ (year)	
Eligible Criteria				
1	Aged between 18 and 60 years old on the day of screening	☐ Yes	☐0 No	
2	Able to provide written informed consent prior to any study procedure	☐ Yes	☐0 No	
3	Pregnancy *(for male, please check "NA")*	☐0 Yes	☐ No	☐ NA
4	Willing to take reliable birth control measures for 1 month after vaccination *(for male, please check "NA")*	☐ Yes	☐0 No	☐ NA
5	Lactating *(for male, please check "NA")*	☐0 Yes	☐ No	☐ NA
6	Receive any vaccine within 4 weeks preceding the trial	☐0 Yes	☐ No	
7	Plan to receive vaccine during 3 weeks following the trial	☐0 Yes	☐ No	
8	Vaccination against influenza in the past 6 months	☐0 Yes	☐ No	
9	Self-reported history of influenza infection in the past 6 months	☐0 Yes	☐ No	
10	Chronic illness that might interfere with the trial or increase participant risk	☐0 Yes	☐ No	
11	History of anaphylactic reaction to previous influenza vaccine	☐0 Yes	☐ No	
12	History of Guillain-Barre' syndrome (GBS) within 6 weeks after previous dose of influenza vaccine	☐0 Yes	☐ No	
13	Current medication of immunosuppressive agents	☐ Yes	☐ No	
14	Bleeding disorders or current anticoagulant/antiplatelet drug use	☐ Yes	☐ No	
15	Able to attend all scheduled visits and comply with all procedures	☐ Yes	☐0 No	
Laboratory				
16	Urine Pregnancy test *(for male, please check "NA")*	☐0 Positive	☐ Negative	☐ NA
Screening Result				
17	Is participant eligible for criteria (*Check No, if any checkbox* ☐0 in this form)	☐ Yes	☐ No	
18	Assigned Random ID	☐☐☐		

S101: Immunogenicity and Safety of a Quadrivalent Influenza Vaccine Given Intramuscularly in Participants Aged 18 to 60 Years

CRF02 | Enrollment Form

Site No. ☐ Random ID. ☐☐☐ Initials ☐☐ Date of visit ☐☐ (day) ☐☐ (month) ☐☐☐☐ (year)

Demographic

1	Informed Consent	Date of Informed Consent Form Signed ☐☐ (day) ☐☐ (month) ☐☐☐☐ (year)	Time of Informed Consent Form Signed *(24-hr Format)* ☐☐ (hour) : ☐☐ (minute)
2	Year of Birth	☐☐☐☐	
3	Sex (biologically determined)	☐ Male ☐ Female	
4	Race	☐ Asian ☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Black or African American ☐ Tribe ☐ Other, specify	

Vital Signs

5	Height	☐☐☐ . ☐ cm	
6	Weight	☐☐☐ . ☐ kg	
7	Blood pressure	Systolic ☐☐☐ mmHg	Diastolic ☐☐ mmHg
8	Pulse Rate	☐☐☐ beats per minute	
9	Respiratory rate	☐☐ times per minute	
10	Body Temperature	☐☐ . ☐ °C	

Physical Examination

11	HEENT	☐ Normal	☐ Abnormal, specify .....
12	Cardiovascular	☐ Normal	☐ Abnormal, specify .....
13	Chest	☐ Normal	☐ Abnormal, specify .....
14	Abdomen	☐ Normal	☐ Abnormal, specify .....
15	Musculoskeletal	☐ Normal	☐ Abnormal, specify .....
16	Neurological	☐ Normal	☐ Abnormal, specify .....
17	Review of other Body system	☐ Normal	☐ Abnormal, specify .....

Eligible Check

18	Is the participant eligible to take part in this study	☐ Yes	☐ No

Laboratory

19	Laboratory	Date of Sample Collection ☐☐ (day) ☐☐ (month) ☐☐☐☐ (year)	Time of Sample Collection *(24-hr Format)* ☐☐ (hour) : ☐☐ (minute)
20	A/H1N1 Antibody Titer	☐☐☐ . ☐☐	
21	A/H3N1 Antibody Titer	☐☐☐ . ☐☐	
22	B/Yamagata-lineage Antibody Titer	☐☐☐ . ☐☐	
23	B/Victoria-lineage Antibody Titier	☐☐☐ . ☐☐	

Vaccine Administration

24	Vaccination	Date of vaccination ☐☐ (day) ☐☐ (month) ☐☐☐☐ (year)	Time of vaccination *(24-hr Format)* ☐☐ (hour) : ☐☐ (minute)
25	Vaccination Arm	☐ QIV	☐ TIV