IBM Clinical Development

IBM Clinical Development Blank CRFs

Study Name	MINDS-ACHD MSU 3
Generated	10-FEB-22 16:00:00 GMT

Table of Contents

MSU 3 - protocol amendment 5 (new inclusion/exclusion)

Schedule

Table

Unique Identifier	Visit	Visit - Page	Visit ID, Page ID	Notes
visit-10	Pre-Screening		10	Added: On Add Subject
		Pre-Screening	10,10	
visit-20	Screening		20	Added: by visit schedule rule(s) #65
		Informed Consent	20,10	
		Inclusion / Exclusion Criteria	20,20	Added by visit schedule rule(s) #67
visit-30	Main Coordinator Forms		30	Added: by visit schedule rule(s) #70, #77
		Visit Information	30,30	
		Measurements	30,50	
		Heart Medical History	30,60	
		Heart Surgery History	30,70	
		General Medical History	30,80	
		Biorepository Sample Receipt and Processing Form	30,90	Added by visit schedule rule(s) #68, #74, #78
		Participant Behavior	30,120	
		Neuropsychology Recommendation	30,110	
		Census Data	30,130	
		End of Study	30,100	
visit-40	Current Medications		40	Added: by visit schedule rule(s) #71, #76
		Current Medications	40,10	
		Additional Current Medications	40,20	Repeats, Maximum= Unlimited
visit-50	Participant Forms		50	Added: by visit schedule rule(s) #72, #109
		Basic Demographics	50,10	
		Additional Demographics	50,20	
		Psychiatric and Substance History	50,30	

Unique Identifier	Visit	Visit - Page	Visit ID, Page ID	Notes
		Hospital Anxiety and Depression Scale (HADS)	50,40	
visit-60	Adverse Event		60	Added: By User After Add Subject Repeats, Maximum=Unlimited
		Adverse Event Initial Report	60,10	
		Adverse Event Follow Up	60,20	Added by visit schedule rule(s) #87
visit-70	Protocol Deviation		70	Added: By User After Add Subject
		Protocol Deviation	70,10	Repeats, Maximum= Unlimited

Pre-Screening

Pre-Screening

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 10 / Visit Display Name = Pre-Screening / Visit Abbrev = PRSCN / PageID = 10 / Page Display Name = Pre-Screening / Description = Prescreening form updated for protocol 2/1/21)

Section A. GENERAL INFORMATION		
* A1. Study ID Number		(format xxxxxx) Participant ID must match the ID in the database
Section B. PRE-SCREENING INFORMATION		
* B1. Does the subject appear to meet inclusion criteria based on the information available?	○ Yes ○ No	
Inclusion Criteria: **Age 18-30** **CHD (repaired or unrepaired) of moderate or severe complexity**		
* B2. Biological sex	○ Male ○ Female	
* B3. Does the PI plan to approach the potential participant about the study:	○ Yes ○ No	
* B3a. If no, please provide reason why.		
B4. How will this subject be approached? Check all that apply.		
* B4a. Recruitment Letter	○ Yes ○ No	
* B4a1. If yes, date initial letter sent to participant		(DD-MMM-YYYY)

* B4a2. If yes, did the participant respond?	○ Yes ○ No	
* B4a3. If yes, response date		(DD-MMM-YYYY)
* B4a4. If no, was a follow-up letter sent?	○ Yes ○ No	
* B4a5. If yes, date sent (should be within 1 month of original letter)		(DD-MMM-YYYY)
* B4a6. Did the participant respond to the follow up letter?	○ Yes ○ No	
* B4a7. If yes, date of participant response		(DD-MMM-YYYY)
* B4b. On the phone	○ Yes ○ No	
* B4b1. Date called		(DD-MMM-YYYY)
* B4c. By e-mail	○ Yes ○ No	
* B4c1. Date e-mailed		(DD-MMM-YYYY)
* B4d. On the day of their in-person clinic visit	○ Yes ○ No	
* B4d1. Date of visit		(DD-MMM-YYYY)

Screening

Informed Consent

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 20 / Visit Display Name = Screening / Visit Abbrev = SCRN / PageID = 10 / Page Display Name = Informed Consent / Description = Consent updated for protocol 2/1/21)

Section A. GENERAL INFORMATION		
* A1. Study ID Number		(format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.
Section B. INFORMED CONSENT/ASSENT		
* B1. Was consent obtained from the Participant?	○ Yes ○ No	
* B2. Method in which consent was obtained:	○ Pen and paper ○ eConsent	
If method of consent was "Written paper" please choose "Pen and paper"		
* B3. Date consent signed		(DD-MMM-YYYY)
* B4. Reason for not obtaining informed consent	○ Participant not interested in participating in research study ○ Attending/Primary physician objection ○ Language Barrier ○ Other	
* B5. If Reason for not obtaining informed consent is "Other" please specify:		

ALERT: If consent was not obtained, the participant is not eligible to participate in the study.

Section C. BIOBANK BLOOD OR SALIVA CONSENT

* C1. Was consent obtained from the Participant for the Biobank sample?	○ Yes ○ No	
* C2. Date consent signed		(DD-MMM-YYYY)
* C3. Reason for not obtaining Biobank sample consent	○ Participant not interested in participating in the research study ○ Attending primary physician objection ○ Language Barrier ○ Participant uncomfortable with the idea of genetic testing ○ Other	
* C4. If C3. is "Other" please specify:		
* C5. Did the participant agree to have data and samples shared in a central biobank for future studies?	○ Yes ○ No	
* C6. Did the participant agree to be contacted in the future for return of results of genetic testing?	○ Yes ○ No	
* C7. Did the participant agree to be contacted in the future to collect health information about him/her and his/her family and/or offered participation in new studies?	○ Yes ○ No	

Inclusion / Exclusion Criteria

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 20 / Visit Display Name = Screening / Visit Abbrev = SCRN / PageID = 20 / Page Display Name = Inclusion / Exclusion Criteria / Description = Inclusion/Exclusion updated for protocol 12/13/21)

Section A. GENERAL INFORMATION		
* A1. Study ID Number		(format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.
Section B. INCLUSION CRITERIA		
* B1. Age 18-30 years	○ Yes ○ No	
B2. CHD (repaired or unrepaired) of moderate or severe complexity - QUESTEION HIDDEN	○ Yes ○ No	
* B2. Current CHD (repaired or unrepaired) of moderate or severe complexity	○ Yes ○ No	
* B3. English language proficiency	○ Yes ○ No	
Section C. EXCLUSION CRITERIA		
* C1. CHD of mild complexity	○ Yes ○ No	
* C2. Prior heart transplant to treat CHD	○ Yes ○ No	
* C3. Heart disease that is not classified as structural CHD (e.g., connective tissue disease, genetic cardiomyopathy, or acquired heart disease)	○ Yes ○ No	
* C4. Current pregnancy or within 3 months post-partum	○ Yes ○ No	
* C5. Inpatient or hospitalized at time of consent or study measures	○ Yes ○ No	

* C6. Any procedures requiring conscious sedation or general anesthesia within past 3 months from time of consent	○ Yes ○ No	
C3. Inability to complete the surveys or testing - QUESTION HIDDEN	○ Yes ○ No	
* C7. Inability to complete the surveys or testing independently	○ Yes ○ No	
* C8. Prior completion of the NIH Toolbox Cognitive Battery at any time	○ Yes ○ No	

Participants with known genetic syndromes will not be excluded from the study unless they meet one of the other exclusion criteria

* C9. No access to a computer or tablet for testing and/or no strong internet connection (remote visit only)	○ Yes ○ No ○ Not Applicable	

If the participant will do some or all study procedures remotely, please select “Yes” or “No.” Please select “Not Applicable” only if the participant will do all study procedures in-person.

Eligibility - QUESTION HIDDEN	(auto calculated)	(format x)
Eligibility	(auto calculated)	(format x)

Main Coordinator Forms

Visit Information

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 30 / Visit Display Name = Main Coordinator Forms / Visit Abbrev = COORD / PageID = 30 / Page Display Name = Visit Information / Description = Visit Information updated for protocol 2/1/21)

Section A. GENERAL INFORMATION		
* A1. Study ID Number		(format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.
Section B. VISIT INFORMATION		
* B1. Coordinator Forms completed by:		
* B2. Date Coordinator Forms were completed		(DD-MMM-YYYY)
* B3. Visit was conducted as:	○ Part of a routine clinic visit ○ A separate research visit ○ Both (participant came in more than once for study)	
* B4. Visit type:	○ Complete in-person ○ Completely remote ○ Both in-person and remote	

Please select “Both in-person and remote” in situations where there were both remote questionnaires and in-person biospecimen collection.

Measurements

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 30 / Visit Display Name = Main Coordinator Forms / Visit Abbrev = COORD / PageID = 50 / Page Display Name = Measurements / Description = Measurements)

Section A. GENERAL INFORMATION		
* A1. Study ID Number		(format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.
* A2. Please select the participant's heart condition:	○ d-transposition of the great arteries (TGA) ○ tetralogy of Fallot (TOF) ○ single ventricle ○ other moderate and severely complex CHD lesions	
Section B. MEASUREMENTS		
* B1. Were height and weight collected?	○ Yes ○ No	
* B1a. Date that measurements were collected		(DD-MMM-YYYY)
* B1b. Height (cm):		(format xxx.xx)
* B1c. Weight (kg):		(format xxx.xx)
* B1d. BMI (kg/m2)	(auto calculated)	(format xxx.xx)

Heart Medical History

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 30 / Visit Display Name = Main Coordinator Forms / Visit Abbrev = COORD / PageID = 60 / Page Display Name = Heart Medical History / Description = Heart Medical History updated for protocol 1/10/22)

Section A. GENERAL INFORMATION

* A1. Study ID Number		(format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.

Section B: CONGENITAL HEART DISEASE (CHD) COMPLEXITY

Include all diagnosis for which the participant is being seen in an ACHD program for follow-up regarding possible sequelae of the initial diagnosis or intervention. For example, include all diagnoses that were dealt with by a surgery or interventional procedure. Include all major residual lesions after surgeries and/or interventional procedures. If a diagnosis resolved on its own (e.g., a secundum atrial septal defect that closed spontaneously), then do not include it. Please do not include surgeries on the medical history form; instead, please enter them only on the surgical form.

B1. Moderate CHD:

* B1a. Aorto-left ventricular fistula	○	Yes
	○	No
* B1b. Anomalous pulmonary venous connection, partial or total	○	Total
	○	Partial
	○	Not present
* B1c. Anomalous coronary artery arising from the pulmonary artery	○	Yes
	○	No
* B1d. Anomalous aortic origin of a coronary artery from the opposite sinus	○	Right coronary from left sinus
	○	Left coronary from right sinus
	○	Other
	○	Not present
* B1e. Atrioventricular septal defects (partial or complete, including primum ASD)	○	Complete
	○	Partial
	○	Not present

* B1f. Congenital aortic valve disease (including bicuspid aortic valve)	○	Yes
	○	No
B1f1. Please specify congenital aortic valve disease	☐	Unicuspid aortic valve
	☐	Bicuspid aortic valve
	☐	Quadricuspid aortic valve
	☐	Aortic stenosis
	☐	Aortic insufficiency
Select all that apply		
* B1g. Congenital mitral valve disease	○	Yes
	○	No
B1g1. Please specify congenital mitral valve disease	☐	Mitral stenosis
	☐	Mitral insufficiency
	☐	Mitral arcade
	☐	Parachute mitral valve
Select all that apply		
* B1h. Coarctation of the aorta	○	Yes
	○	No
* B1i. Ebstein's anomaly (disease spectrum includes mild, moderate, and severe variations)	○	Yes
	○	No
* B1j. Infundibular right ventricular outflow obstruction	○	Yes
	○	No
* B1k. Ostium primum atrial septal defect	○	Yes
	○	No
* B1l. Moderate and large unrepaired secundum atrial septal defect	○	Moderate
	○	Large
	○	Not present

* B1m. Moderate and large persistently patent ductus arteriosus	○	Moderate
	○	Large
	○	Not present
Patent ductus arteriosus (clinically important) (hidden from sites in Rev2)	○	Yes
	○	No
* B1n. Pulmonary valve regurgitation (moderate or greater)	○	Present - Severe
	○	Present - Moderate
	○	Not present
* B1o. Pulmonary valve stenosis (moderate or greater)	○	Present - Severe
	○	Present - Moderate
	○	Not present
* B1p. Peripheral pulmonary stenosis	○	Present - Severe
	○	Present - Moderate
	○	Not present
* B1q. Sinus of Valsalva fistula/aneurysm	○	Yes
	○	No
* B1r. Sinus venosus defect	○	Yes
	○	No
* B1s. Subvalvular aortic stenosis (excluding hypertrophic cardiomyopathy)	○	Yes
	○	No
* B1t. Supravalvular aortic stenosis	○	Yes
	○	No
* B1u. Straddling atrioventricular valve	○	Yes
	○	No
* B1v. Tetralogy of Fallot (includes Pulmonary Atresia/Ventricular Septal Defect and Tetralogy of Fallot/Atrioventricular Septal Defect)	○	Yes
	○	No

* B1w. Ventricular septal defects with (any of the associated factors below and/or moderate or greater shunt)	○ Yes ○ No
* B1x. Specify all associated features with the ventricular septal defect	☐ aortic regurgitation ☐ absent pulmonary valve ☐ aortic coarctation ☐ right ventricular outflow tract obstruction ☐ straddling tricuspid or mitral valve ☐ mitral valve disease ☐ subaortic stenosis
B2. Severe CHD:	
B2a. Conduits: valved or non-valved (hidden from sites in Rev2)	○ Valved ○ Non-valved ○ Not present
* B2a. Cyanotic congenital heart defect (unrepaired or palliated, all forms)	○ Yes ○ No
B2a1. Please specify the cyanotic congenital heart defect	
* B2b. Double outlet ventricle	○ Yes ○ No
* B2c. Fontan procedure	○ Extracardiac ○ Lateral Tunnel ○ Atriopulmonary ○ Other ○ Not done
* B2d. Interrupted aortic arch	○ Yes ○ No

* B2e. Mitral atresia	○	Yes
	○	No
B2c. Eisenmenger Syndrome (hidden from sites in Rev2)	○	Yes
	○	No
* B2f. Single ventricle physiology	○	morphological right ventricle
	○	morphological left ventricle
	○	mixed ventricular morphology
	○	not present
Pulmonary vascular obstructive disease (hidden from sites in Rev2)	○	Yes
	○	No
* B2g. Pulmonary atresia (no Ventricular Septal Defect)	○	Pulmonary atresia/Intact ventricular septum
	○	Other
	○	Not present
* B2h. D- Transposition of the great arteries	○	Yes
	○	No
B2i. L- Transposition of the great arteries	○	Yes
	○	No
* B2j. Truncus arteriosus	○	Yes
	○	No
B2k. Abnormalities of atrioventricular or ventriculoarterial connection not included above (any of those listed below)	☐	crisscross heart
	☐	isomerism
	☐	heterotaxy syndromes
	☐	ventricular inversion
B3. Other forms of moderate to severe CHD not listed: Please specify:		

If none, please leave blank.

Section C. CYANOTIC CHD

* C1. History of cyanotic CHD:	○ Yes ○ No	
* C1a. If Yes, duration of cyanosis (cumulative in years up to the date of their corrective surgery)	○ < 2 years ○ 2-5 years ○ > 5 years	
* C2. Oxygen saturation at the clinical encounter temporally closest to enrollment (%)		(format xx.xx)
* C2a. Date of the clinical encounter		(DD-MMM-YYYY)

Section D. Heart Function

* D1. New York Heart Association Functional Class	○ I ○ II ○ III ○ IV	

New York Heart Association Functional Class:

I
No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).

II
Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).

III
Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.

IV
Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

Heart Surgery History

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 30 / Visit Display Name = Main Coordinator Forms / Visit Abbrev = COORD / PageID = 70 / Page Display Name = Heart Surgery History / Description = Heart Surgery History updated for protocol 2/1/21)

Section A. GENERAL INFORMATION

* A1. Study ID Number		(format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.

Section B. OPEN HEART SURGERIES

* B1. Number of open-heart surgical procedures requiring cardiopulmonary bypass (CPB; enter up to 9)		(format x)

Surgery Number	Years of age at surgery		Months of age at surgery	
Surgery #1		(xx)		(xx)
Surgery #2		(xx)		(xx)
Surgery #3		(xx)		(xx)
Surgery #4		(xx)		(xx)
Surgery #5		(xx)		(xx)
Surgery #6		(xx)		(xx)
Surgery #7		(xx)		(xx)
Surgery #8		(xx)		(xx)
Surgery #9		(xx)		(xx)

Section C. SURGICAL PROCEDURES

Procedure	Did the participant have the procedure?	Age (years) of first procedure	Age (years) of second procedure (if applicable)	Age (years) of third procedure (if applicable)
C1. ASD closure	○Yes ○No ○Unknown	(xx)	(xx)	(xx)
C2. VSD closure	○Yes ○No ○Unknown	(xx)	(xx)	(xx)
C3. PDA closure	○Yes ○No ○Unknown	(xx)	(xx)	(xx)
C4. Atrial septostomy	○Yes ○No ○Unknown	(xx)	(xx)	(xx)
C5. Blalock-Taussig shunt	○Yes ○No ○Unknown	(xx)	(xx)	(xx)
C6. Glenn shunt	○Yes ○No ○Unknown	(xx)	(xx)	(xx)
C7. Kawashima/ Hepatic Inclusion Only Fontan	○Yes ○No ○Unknown	(xx)	(xx)	(xx)
C8. Potts shunt/anastomosis	○Yes ○No ○Unknown	(xx)	(xx)	(xx)

C9. Waterston shunt/anastomosis	○Yes ○No ○Unknown		(xx)		(xx)		(xx)
C10. TOF repair	○Yes ○No ○Unknown		(xx)		(xx)		(xx)
C11. Aortic coarctation repair	○Yes ○No ○Unknown		(xx)		(xx)		(xx)
C12. Ross procedure	○Yes ○No ○Unknown		(xx)		(xx)		(xx)
C13. Repair of Aorta – Left ventricular fistula	○Yes ○No ○Unknown		(xx)		(xx)		(xx)
C14. Mustard or Senning procedure	○Yes ○No ○Unknown		(xx)		(xx)		(xx)
C15. Brock procedure	○Yes ○No ○Unknown		(xx)		(xx)		(xx)
C16. Rastelli procedure	○Yes ○No ○Unknown		(xx)		(xx)		(xx)
C17. Double switch procedure	○Yes ○No ○Unknown		(xx)		(xx)		(xx)

C18. Arterial switch procedure	○Yes ○No ○Unknown		(xx)		(xx)		(xx)
C19. Norwood procedure	○Yes ○No ○Unknown		(xx)		(xx)		(xx)

Section D. FONTAN PROCEDURE

* D1. Did the participant have the Fontan procedure?	○ Yes ○ No ○ Unknown	
D1a. Age when Right Atrium to Pulmonary Artery surgery was done (in years)		(format xx)
D1b. Age when Right Ventricle to Pulmonary Artery surgery was done (in years) - QUESTION HIDDEN		(format xx)
D1b. Age when 'Other' type of Fontan surgery was done (in years)		(format xx)
* D1c. Age when lateral tunnel surgery was done (in years)		(format xx)
D1d. Age when extracardiac conduit surgery was done (in years)		(format xx)

Section E. ADDITIONAL SURGICAL HISTORY

Procedure	Did the participant have the procedure?	Age (years) of first procedure	Age (years) of second procedure (if applicable)	Age (years) of third procedure (if applicable)
E1. Hemi-Fontan	○Yes ○No ○Unknown	(xx)	(xx)	(xx)
E2. Surgical Aortic valve repair/replacement	○Yes ○No ○Unknown	(xx)	(xx)	(xx)
E3. Surgical Mitral Valve repair/replacement	○Yes ○No ○Unknown	(xx)	(xx)	(xx)
E4. Surgical Tricuspid Valve repair/replacement	○Yes ○No ○Unknown	(xx)	(xx)	(xx)
E5. Surgical Pulmonary Valve repair/replacement	○Yes ○No ○Unknown	(xx)	(xx)	(xx)
E6. Right ventricular outflow tract surgical repair	○Yes ○No ○Unknown	(xx)	(xx)	(xx)
E7. Left ventricular outflow tract surgical repair	○Yes ○No ○Unknown	(xx)	(xx)	(xx)
E8. Unifocalization of Major Aorto-Pulmonary Collateral Arteries	○Yes ○No ○Unknown	(xx)	(xx)	(xx)

Section F. OTHER PROCEDURES

* F1. If the participant had any other cardiac procedures not listed above, please input the number of additional procedures.		(format x)

Procedure Name	Age in years	
		(xx)
		(xx)
		(xx)
		(xx)
		(xx)
		(xx)
		(xx)
		(xx)
		(xx)

Section G. INTERVENTIONAL CATHETERIZATION HISTORY

* G1. Number of interventional catheterizations (excluding diagnostic cardiac catheterizations and arrhythmia interventions):		(format xx)

General Medical History

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 30 / Visit Display Name = Main Coordinator Forms / Visit Abbrev = COORD / PageID = 80 / Page Display Name = General Medical History / Description = General Medical History updated for protocol 2/1/21)

Section A. GENERAL INFORMATION

* A1. Study ID Number _____ (format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.

Please enter the current (within the last 3 months)/past history of medical comorbidities based on diagnoses listed in medical records below.

Section B. CONGESTIVE HEART FAILURE

* B1. Congestive Heart Failure

- ○ Yes
- ○ No

Type	Current (within the past 3 months)	Past
B1a. Morphological Right Ventricle Failure	○ Yes ○ No	○ Yes ○ No
B1b. Morphological Left Ventricle Failure	○ Yes ○ No	○ Yes ○ No
B1c. Single Ventricle: Morphological Right Ventricle Failure	○ Yes ○ No	○ Yes ○ No
B1d. Single Ventricle: Morphological Left Ventricle Failure	○ Yes ○ No	○ Yes ○ No
B1e. Single Mixed	○ Yes ○ No	○ Yes ○ No
Section C. MEDICAL COMORBIDITIES	**Current (within the past 3 months)**	**Past**
C1. Hypertension:	○ Yes ○ No	○ Yes ○ No
C2. Diabetes mellitus (all types):	○ Yes ○ No	○ Yes ○ No
C3. Liver Cirrhosis	○ Yes ○ No	○ Yes ○ No
C4. Chronic kidney disease ≥ Stage III (GFR ≤ of 30-59 ml/min/1.73 m2)	○ Yes ○ No	○ Yes ○ No
C5. Seizures	○ Yes ○ No	○ Yes ○ No
C6. Choreoathetosis	○ Yes ○ No	○ Yes ○ No ○ Unknown
C7. Meningitis (hidden from sites in Rev2)	○ Yes ○ No	○ Yes ○ No ○ Unknown

C8. Coma (hidden from sites in Rev2)	○ Yes ○ No	○ Yes ○ No ○ Unknown
C9. Diagnosis of ADD or ADHD (hidden from sites in Rev2)	○ Yes ○ No	○ Yes ○ No ○ Unknown
C10. Diagnosis of learning disability (hidden from sites in Rev2)	○ Yes ○ No	○ Yes ○ No ○ Unknown
C11. Autism (hidden from sites in Rev2)	○ Yes ○ No	○ Yes ○ No ○ Unknown
C12. Asperger's Disorder (hidden from sites in Rev2)	○ Yes ○ No	○ Yes ○ No ○ Unknown
C13. Traumatic (closed/open) head injury with loss of consciousness > 30 minutes (hidden from sites in Rev2)	○ Yes ○ No	○ Yes ○ No
C14. Hypoxic ischemic neurological insult (hidden from sites in Rev2)	○ Yes ○ No	○ Yes ○ No
C7. Obesity (BMI >25.0 measured in kg/m2)	○ Yes ○ No	○ Yes ○ No

Section C. MEDICAL COMORBIDITIES (continued)

* C8. Meningitis	○ Yes ○ No ○ Unknown
* C9. Coma	○ Yes ○ No ○ Unknown

* C10. Diagnosis of ADD or ADHD	○	Yes
	○	No
	○	Unknown
* C11. Diagnosis of learning disability	○	Yes
	○	No
	○	Unknown
* C12. Autism	○	Yes
	○	No
	○	Unknown
* C13. Asperger's Disorder	○	Yes
	○	No
	○	Unknown
* C14. Traumatic (closed/open) head injury with loss of consciousness > 30 minutes	○	Yes
	○	No
	○	Unknown
* C15. Hypoxic ischemic neurological insult	○	Yes
	○	No
	○	Unknown
Section D. CEREBROVASCULAR ACCIDENTS		
* D1. Cerebrovascular Accident (TIA or stroke, past or current)	○	Yes
	○	No

Type	Current (within the past 3 months)	Past
D1a. Transient ischemic attack (TIA) (hidden from sites in Rev2)	○ Yes ○ No	○ Yes ○ No
D1b. Ischemic stroke (hidden from sites in Rev2)	○ Yes ○ No	○ Yes ○ No
D1c. Hemorrhagic stroke (hidden from sites in Rev2)	○ Yes ○ No	○ Yes ○ No
D1d. Mixed ischemic and hemorrhagic stroke (hidden from sites in Rev2)	○ Yes ○ No	○ Yes ○ No
D1e. Unknown type of stroke (hidden from sites in Rev2)	○ Yes ○ No	○ Yes ○ No

* D1a. Transient ischemic attack (TIA)	○ Yes ○ No ○ Unknown
* D1b. Ischemic stroke	○ Yes ○ No ○ Unknown
* D1c. Hemorrhagic stroke	○ Yes ○ No ○ Unknown
* D1d. Mixed ischemic and hemorrhagic stroke	○ Yes ○ No ○ Unknown
* D1e. Unknown type of stroke	○ Yes ○ No ○ Unknown

Section E. THYROID DISORDERS

* E1. Thyroid disorders (past or current)	○ Yes ○ No	
Type	Current (within the past 3 months)	Past
E1a. Hypothyroidism	○ Yes ○ No	○ Yes ○ No
E1b. Hyperthyroidism	○ Yes ○ No	○ Yes ○ No

Section F. ARRHYTHMIA		
* F1. Arrhythmia (past or current)	○ Yes ○ No	
Type	Current (within the past 3 months)	Past
F1a. Atrial	○ Yes ○ No	○ Yes ○ No
F1b. Ventricular	○ Yes ○ No	○ Yes ○ No
F1c. Heart Block (Mobitz Type II or 3rd Degree Only):	○ Yes ○ No	○ Yes ○ No

Section G. MALIGNANCY (If the participant has current or past history of malignancy, please specify below. If none, please leave blank.)	Current (within the past 3 months)	Past
	○ Yes ○ No	○ Yes ○ No
	○ Yes ○ No	○ Yes ○ No
	○ Yes ○ No	○ Yes ○ No

Section H. GENETIC DISORDER (If the participant has any genetic disorders, please specify below. If none, please leave blank.)

Specify

Specify	
Specify	

Section H. GENETIC DISORDER (hidden from sites in Rev2)	
Current (within the past 3 months)	Past
○ Yes ○ No	○ Yes ○ No
○ Yes ○ No	○ Yes ○ No
○ Yes ○ No	○ Yes ○ No

Section I. DEVICES/TESTS	
* I1. Placement of an Implantable Cardioverter Defibrillator	○ Yes ○ No
* I2. Placement of a Pacemaker:	○ Yes ○ No
* I3. Placement of a Cardiac Resynchronization Therapy device	○ Yes ○ No
* I4. Prior electrophysiological ablation	○ Yes ○ No

Biorepository Sample Receipt and Processing Form

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 30 / Visit Display Name = Main Coordinator Forms / Visit Abbrev = COORD / PageID = 90 / Page Display Name = Biorepository Sample Receipt and Processing Form / Description = Biorepository Sample Collection Form)

Section A. GENERAL INFORMATION		
* A1. Study ID Number		(format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.
* A2. Biorepository ID (format: XXXX-XX)		The sample ID should be in the format MINDS-XXXX-XX. Please do not include the "MINDS-" text but do include XXXX-XX with the dash.
Section B: BIOSPECIMEN COLLECTION		
* B1. Type of specimen collected (if applicable):	○ Blood/Plasma ○ Saliva ○ Not collected	
* B2. Date of sample collection		(DD-MMM-YYYY)
* B3. Specimen stored at:	○ Ambient Temp ○ Frozen (-80 degrees C) ○ Other (please specify below)	
* B3a. Specify temperature in Celcius:		(format xxx.xx)
* B4. Was the sample shipped to the Biorepository?	○ Yes ○ No	
* B4a. Shipped at:	○ Ambient Temp ○ Frozen (-80 degrees C) ○ Other (please specify below)	
* B4b. Other temperature shipped at (in Celcius):		(format xxx.xx)
* B4c. Date sample was shipped:		(DD-MMM-YYYY)

* B4d. Airbill Number	
* B5. Reason sample not collected:	

Participant Behavior

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 30 / Visit Display Name = Main Coordinator Forms / Visit Abbrev = COORD / PageID = 120 / Page Display Name = Participant Behavior / Description = Participant Behavior)

Section A. GENERAL INFORMATION

* A1. Study ID Number		(format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.

Section B. PARTICIPANT BEHAVIOR

Some key observations for consideration are:

Poor effort—examinees may not give best effort for a variety of reasons (don't care, give up easily when challenged, very anxious, may intentionally not looking at the screen).
Environmental interruptions/disruptions (fire alarm testing; people talking loudly outside of the examination room; examinee/er forgot to turn off cell phone, etc.)
Examinee does not understand a task or forgot the instructions after the test started
The participant is too low functioning
Examinee highly inattentive (e.g., didn't look at screen because distracted)
Examinee sleepy/hypersomnolent
Examinee's hearing or vision issues could impact certain tests
Examiner administration errors
Disruption in technology
Examination discontinued (e.g., examinee refused to finish)

* B1. Behavior noted during HADS administration:	
* B2. Behavior noted during Cognitive battery administration:	

* B3. Behavior noted during Neuro-QOL administration:	
* B4. Behavior noted during PROMIS adninistration:	

Neuropsychology Recommendation

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 30 / Visit Display Name = Main Coordinator Forms / Visit Abbrev = COORD / PageID = 110 / Page Display Name = Neuropsychology Recommendation / Description = Neuropsychology Recommendation)

This page is to be filled out by the neuropsychologist and affiliated personnel only.

Section A. GENERAL INFORMATION

* A1. Study ID Number		(format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.

Section B. NEUROPSYCHOLOGY REVIEW

* B1. Date neurocognitive results reviewed:		(DD-MMM-YYYY)
* B2. Status of data reviewed:	○ Complete ○ Incomplete/missing (e.g., did not finish or a questionnaire not done)	
* B2a. Please specify which data was incomplete or missing:		

Section C. OUTCOME OF REVIEW/RECOMMENDATION TO PARTICIPANT'S PRIMARY CARDIOLOGIST

* C1. Consider referral for more comprehensive neuropsychological evaluation	○ Yes ○ No ○ Uncertain

* C1a. Consider offering participant referral for comprehensive neuropsychological testing due to:	○ Reported cognitive complaints on questionnaire AND deficits or notable weaknesses on NIH Toolbox cognitive measures. ○ Notable cognitive complaints on questionnaire, despite normal performance on NIH Toolbox ○ Deficits or notable weaknesses on the NIH Toolbox cognitive measures, despite no cognitive complaints on questionnaire. ○ Self-report cognitive symptoms and/or NIH toolbox objective data were considerably benign, please contact participant to determine if he/she would be interested in a referral for comprehensive neuropsychological testing.
* C1YES. If yes, the following objective cognitive tests scores were identified as low relative to a normative sample:	☐ attention & executive functioning ☐ episodic memory ☐ working memory ☐ language ☐ processing speed
* C1YES. If yes, the following objective cognitive tests scores were identified as subtly low relative to a normative sample:	☐ attention & executive functioning ☐ episodic memory ☐ working memory ☐ language ☐ processing speed

C1NO. Based on review of NIH questionnaire and objective cognitive measures, there is no clear indication that comprehensive neuropsychological evaluation is needed.

* C1UNCERTAIN. Uncertain, based on the following:	○ Data is missing and no opinion can be formed ○ Other (specify below)
* C1UNCERTAIN(b). Please explain:	
* C2. Consider mental health referral	○ Yes ○ No ○ Uncertain

* C2YES. Consider mental health referral because:	○	The participant had an abnormal HADS score and referral to psychiatrist and/or psychotherapist should be considered, in light of presence or absence of current mental health treatment. If no specific mental health providers are known, advise participant to contact insurance company for a list of in-network providers. Psychologytoday.com also is a great resource to view local psychotherapists who should take their insurance.
	○	The participant had a borderline abnormal HADS score and referral to psychiatrist and/or psychotherapist should be considered, in light of presence or absence of current mental health treatment. If no specific mental health providers are known, advise participant to contact insurance company for a list of in-network providers. Psychologytoday.com also is a great resource to view local psychotherapists who should take their insurance.

C2NO. Based on review of HADS and QOL measures, there is no clear indication that there is a need for a mental health referral.

* C2UNCERTAIN. Uncertain, based on the following:	○	Data is missing and no opinion can be formed
	○	Other (specify below)

* C2UNCERTAIN(b). Please explain:	
C3. Additional comments, if applicable	

Census Data

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 30 / Visit Display Name = Main Coordinator Forms / Visit Abbrev = COORD / PageID = 130 / Page Display Name = Census Data / Description = Census Data created for protocol 2/1/22)

* 1. Country of current residence	○ United States ○ Canada ○ Other ○ Decline to answer
* 1a. Other, please specify:	

* 2. State of current residence in the United States

- ○ Alabama
- ○ Alaska
- ○ Arizona
- ○ Arkansas
- ○ California
- ○ Colorado
- ○ Connecticut
- ○ Dist. Columbia
- ○ Delaware
- ○ Florida
- ○ Georgia
- ○ Hawaii
- ○ Idaho
- ○ Illinois
- ○ Indiana
- ○ Iowa
- ○ Kansas
- ○ Kentucky
- ○ Louisiana
- ○ Maine
- ○ Maryland
- ○ Massachusetts
- ○ Michigan
- ○ Minnesota
- ○ Mississippi
- ○ Missouri
- ○ Montana
- ○ Nebraska

- ○ Nevada
- ○ New Hampshire
- ○ New Jersey
- ○ New Mexico
- ○ New York
- ○ North Carolina
- ○ North Dakota
- ○ Ohio
- ○ Oklahoma
- ○ Oregon
- ○ Pennsylvania
- ○ Rhode Island
- ○ South Carolina
- ○ South Dakota
- ○ Tennessee
- ○ Texas
- ○ Utah
- ○ Vermont
- ○ Virginia
- ○ Washington
- ○ West Virginia
- ○ Wisconsin
- ○ Wyoming
- ○ Other
- ○ Decline to answer

* 2a. Other:

* 3. Zip code in the United States (format xxxxx)

For US participants, please enter the census tract and include 2 digits after the decimal point (if none provided, use .00)

* 4. Census Tract (US Only)		(format xxxx.xx)
For US participants, please enter the 4-digit census block		
* 5. Census Block Code (US Only)		(format xxxx)
* 6. Province in Canada	○ Alberta ○ British Columbia ○ North West Terr ○ Saskatchewan ○ Labrador ○ Manitoba ○ Ontario ○ Yukon ○ New Brunswick ○ Newfoundland ○ Prince Edward Is ○ Nova Scotia ○ Nunavut ○ Quebec ○ Other ○ Decline to answer	
* 6a. Other:		
* 7. FSA in Canada		
For Canadian participants, please enter the 7-digit census tract and include 2 digits after the decimal point (if none provided, use .00)		
* 8. Census Tract (Canada Only)		(format xxxxxxx.xx)
For Canadian participants, please enter the 8-digit Dissemination Area		
* 9. Dissemination Area (Canada Only)		(format xxxxxxxx)

End of Study

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 30 / Visit Display Name = Main Coordinator Forms / Visit Abbrev = COORD / PageID = 100 / Page Display Name = End of Study / Description = End of Study updated for protocol 2/1/21)

Section A. GENERAL INFORMATION

* A1. Study ID Number _____ (format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.

Section B: END OF STUDY

* B1. End of study reason:

- ○ Participant not enrolled
- ○ Study completed
- ○ Physician decision to withdraw
- ○ Participant decision to withdraw
- ○ Lost to follow-up
- ○ Site closed
- ○ Study closed
- ○ Death

Please enter an AE form.

* B2. End of study date: _____ (DD-MMM-YYYY)

B3. Please add comments about the end of study: _____

Section C. CONSENT WITHDRAW

* C1. Was biospecimen consent withdrawn?

- ○ Yes
- ○ No

* C1a. Reason for withdrawing biospecimen consent		
* C1b. Date biospecimen consent was withdrawn		(DD-MMM-YYYY)
* C1c. Was the biospecimen shipped to the lab prior to consent withdrawal?	○ Yes ○ No	
* C2. Did the participant withdraw consent for questionnaire, demographics, or medical history data that was already collected?	○ Yes ○ No	
* C2a. Please select all data/questionnaires for which consent was withdrawn:	☐ NIH Toolbox Cognitive Battery ☐ NeuroQOL Item Bank v2.0 Cognitive Function ☐ Hospital Anxiety and Depression Scale (HADS) ☐ PROMIS Scale v1.2 Global Health ☐ Demographic information (some or all) ☐ Clinical/Medical information (some or all)	
* C2b. Reason for withdrawing consent		

Current Medications

Current Medications

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 40 / Visit Display Name = Current Medications / Visit Abbrev = MEDS / PageID = 10 / Page Display Name = Current Medications / Description = Current Medications updated for MSU 3 12/15/21)

Section A. GENERAL INFORMATION

* A1. Study ID Number		(format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.

Section B. CURRENT MEDICATIONS

Medication	Currently taking this medication?
Beta blocker	○ Yes ○ No
Diuretic	○ Yes ○ No
Spironolactone	○ Yes ○ No
ACE-Inhibitor	○ Yes ○ No
Angiotensin receptor blocker (ARB)	○ Yes ○ No
Aspirin	○ Yes ○ No
Coumadin	○ Yes ○ No
Low molecular weight heparin	○ Yes ○ No
Novel oral anticoagulant agent	○ Yes ○ No
Statin	○ Yes ○ No
Oxygen	○ Yes ○ No
Levothyroxine	○ Yes ○ No

Section C. SPECIFY ADDITIONAL CURRENT MEDICATIONS

'If participant does not take the listed medication, please leave the 'Please Specify' field blank, then indicate in the query response that the medication is not being taken.

Medication	Please specify:
Antiarrhythmic medication	
Anti-seizure medication	
Anti-anxiety medication	
Anti-psychotic medication	
Chronic Narcotic Use (>3 months)	

For additional medications not listed above, please add a page called Current Additional Medications. Add as many pages Current Additional Medications as needed

Additional Current Medications

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 40 / Visit Display Name = Current Medications / Visit Abbrev = MEDS / PageID = 20 (*) / Page Display Name = Additional Current Medications / Description = Additional Current Medication)

Section A. GENERAL INFORMATION

* A1. Study ID Number (format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.

Section B: ADDITIONAL MEDICATION

Instructions: Please add an additional medication that was not listed on the Current Medications page. Multiple forms can be completed for multiple medications.

* B1. Medication

* B2. Frequency	○ Once (1X) ○ Continuous ○ Daily (QD) ○ Every Other Day (QOD) ○ Every Three Days (Q3D) ○ Every Four Days (Q4D) ○ Every Five days (Q5D) ○ Twice per Day (BID) ○ Three times per Day (TID) ○ Four times per Day (QID) ○ Twice per Week (BIS) ○ Three times a Week (TIS) ○ Four times per Week (QIS) ○ Five times per Week ○ Six times per Week ○ As Needed (PRN) ○ Every Hour (QH) ○ Every 2 Hours (Q2H) ○ Every 3 Hours (Q3H) ○ Every 4 Hours (Q4H) ○ Every 5 Hours (Q5H) ○ Every 6 Hours (Q6H) ○ Every 7 Hours (Q7H) ○ Every 8 Hours (Q8H) ○ Every 9 Hours (Q9H) ○ Every 10 Hours (Q10H) ○ Every 11 Hours (Q11H) ○ Every 13 Hours (Q13H)

	○ Every 14 Hours (Q14H) ○ Every 15 Hours (Q15H) ○ Every 16 Hours (Q16H) ○ Every 17 Hours (Q17H) ○ Every 18 Hours (Q18H) ○ Every 19 Hours (Q19H) ○ Every 20 Hours (Q20H) ○ Every 21 Hours (Q21H) ○ Every 22 Hours (Q22H) ○ Every 23 Hours (Q23H) ○ Every week (QS) ○ Every two weeks (Q2S) ○ Every Three Weeks (Q3S) ○ Every Four weeks (Q4S) ○ Every Month (QM) ○ Every two months (Q2M) ○ Every three months (Q3M) ○ Every four months (Q4M) ○ Twice per month (BIM) ○ Unknown (UNK) ○ Other (please specify below)
* B2a. Other, please specify:	

Participant Forms

Basic Demographics

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 50 / Visit Display Name = Participant Forms / Visit Abbrev = PART / PageID = 10 / Page Display Name = Basic Demographics / Description = Basic Demographics updated for protocol 2/1/22)

Section A. GENERAL INFORMATION		
A1. Date Form Completed:		(DD-MMM-YYYY)
A2. Time completed		(HH24:MI)
Section B. DEMOGRAPHICS		
* B1. Primary spoken language	○ English ○ Spanish ○ Both ○ Other ○ Decline to answer	
* B1a. Other, please describe:		
* B2. Sexual orientation identity	○ Heterosexual (straight) ○ Gay or Lesbian ○ Bisexual ○ Queer ○ Other ○ Decline to answer	
* B2a. Other, please describe:		
Section C. EVENTS Have you ever had any of the following?		

* C1. Tutoring	○ Yes ○ No ○ Unknown ○ Decline to answer
* C2. Held back in school	○ Yes ○ No ○ Unknown ○ Decline to answer
* C3. Early intervention	○ Yes ○ No ○ Unknown ○ Decline to answer
* C4. Outpatient occupational therapy (not for an injury)	○ Yes ○ No ○ Unknown ○ Decline to answer
* C5. Outpatient physical therapy (not for an injury)	○ Yes ○ No ○ Unknown ○ Decline to answer
* C6. Special education	○ Yes ○ No ○ Unknown ○ Decline to answer

Section D. RESIDENCE - QUESTION HIDDEN

D1. Country of current residence - QUESTION HIDDEN	○ United States ○ Canada ○ Other ○ Decline to answer
D1a. Other, please specify: - QUESTION HIDDEN	

D2. State of current residence in the United States - QUESTION HIDDEN

- ○ Alabama
- ○ Alaska
- ○ Arizona
- ○ Arkansas
- ○ California
- ○ Colorado
- ○ Connecticut
- ○ Dist. Columbia
- ○ Delaware
- ○ Florida
- ○ Georgia
- ○ Hawaii
- ○ Idaho
- ○ Illinois
- ○ Indiana
- ○ Iowa
- ○ Kansas
- ○ Kentucky
- ○ Louisiana
- ○ Maine
- ○ Maryland
- ○ Massachusetts
- ○ Michigan
- ○ Minnesota
- ○ Mississippi
- ○ Missouri
- ○ Montana
- ○ Nebraska

	○ Nevada ○ New Hampshire ○ New Jersey ○ New Mexico ○ New York ○ North Carolina ○ North Dakota ○ Ohio ○ Oklahoma ○ Oregon ○ Pennsylvania ○ Rhode Island ○ South Carolina ○ South Dakota ○ Tennessee ○ Texas ○ Utah ○ Vermont ○ Virginia ○ Washington ○ West Virginia ○ Wisconsin ○ Wyoming ○ Other ○ Decline to answer	
D2a. Other: - QUESTION HIDDEN		
D3. Zip code in the United States - QUESTION HIDDEN		(format xxxxx)

D4. Province in Canada - QUESTION HIDDEN	○ Alberta ○ British Columbia ○ North West Terr ○ Saskatchewan ○ Labrador ○ Manitoba ○ Ontario ○ Yukon ○ New Brunswick ○ Newfoundland ○ Prince Edward Is ○ Nova Scotia ○ Nunavut ○ Quebec ○ Other ○ Decline to answer
D4a. Other: - QUESTION HIDDEN	
D5. FSA in Canada - QUESTION HIDDEN	
Section D. INSURANCE INFORMATION	
* D1. Insurance Information:	○ Private ○ Public ○ Private and public ○ Unknown ○ None ○ Other ○ Decline to answer
* D1a. Other, please describe:	

Additional Demographics

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 50 / Visit Display Name = Participant Forms / Visit Abbrev = PART / PageID = 20 / Page Display Name = Additional Demographics / Description = Additional Demographics Page updated for protocol 2/1/21)

Section A. GENERAL INFORMATION		
A1. Date Form Completed:		(DD-MMM-YYYY)
A2. Time Form Completed:		(HH24:MI)

Section B. EDUCATION	
* B1. Do you have a history of special education supports with an IEP (individualized education program)?	○ Yes ○ No ○ Unknown ○ Decline to answer
* B2. Do you have a history of one or more classes in a smaller group class (e.g., special education classes)?	○ Yes ○ No ○ Unknown ○ Decline to answer
* B3. Do you have a history of accommodations for testing at school, such as extended time, small group testing, or modified testing?	○ Yes ○ No ○ Unknown ○ Decline to answer
* B4. Do you have a history of repeating a grade due to learning problems?	○ Yes ○ No ○ Unknown ○ Decline to answer

* B5. Do you have a history of attending a private school to address special learning needs?	○ Yes ○ No ○ Unknown ○ Decline to answer	
* B6. Do you have a history of attending a vocational program in high school?	○ Yes ○ No ○ Unknown ○ Decline to answer	
* B7. Are you currently enrolled in school?	○ Yes ○ No ○ Decline to answer	
* B7a. If yes, select one:	○ Full time student (≥30 hours per week) ○ Part time student (less than 30 hours per week) ○ Decline to answer	
* B7b. If yes, please specify educational program:		
Section C. PARTICIPANT'S EMPLOYMENT		
* C1a. Your current employment status	○ Unemployed - not looking for work ○ Unemployed - looking for work ○ Employed - part time (less than 30 hours per week) ○ Employed - full time (30+ hours per week) ○ Homemaker ○ Retired ○ Decline to answer	
* C1b. If working, specify total number of hours per week you typically work		(format xxx.x)

* C2. Your usual employment (check all that apply)	☐ Unemployed ☐ Homemaker ☐ Higher executive, proprietor of large businesses, major professional ☐ Administrator, proprietor of medium-sized businesses ☐ Smaller business owner, farm owner, manager, minor professional, skilled manual workers, craftsmen ☐ Technician, semiprofessional, small business owner ☐ Machine operator and semiskilled worker ☐ Unskilled worker ☐ Farm laborer, service worker ☐ Student ☐ Other (please specify below)
C2a. If employed, specify job title if not listed above	

Section D. RELATIONSHIP INFORMATION

* D1. Relationship status (check one)	○ Married (spouse) ○ Partner (living together) ○ Single ○ Separated ○ Divorced ○ Widowed ○ Decline to answer

Section E. SPOUSE/PARTNER EMPLOYMENT

* E1. Spouse/partner's current employment status	○ Unemployed - not looking for work ○ Unemployed - looking for work ○ Employed - part time (less than 30 hours per week) ○ Employed - full time (30+ hours per week) ○ Homemaker ○ Retired ○ Decline to answer	
* E1a. If spouse/partner is working, specify total number of hours per week the spouse/partner typically works		(format xxx.x)
* E2. Spouse/partner's current student status	○ Student - full time (30+ hours per week) ○ Student - part time(less than 30 hours per week) ○ Not a student ○ Decline to answer	

Section F. LIVING ARRANGEMENTS

* F1. Current living arrangements (select all that apply)	☐	Live alone
	☐	Live with spouse (married)
	☐	Live with partner (long-term relationship)
	☐	Live with parent
	☐	Live with child/children
	☐	Live with grandparent/grandparents
	☐	Live with grandchild/grandchildren
	☐	Live with sibling/siblings
	☐	Live with aunt/uncle
	☐	Live with parent-in-law/parents-in-law
	☐	Live with cousin/cousins
	☐	Live with other relatives (specify below)
	☐	Live with friend/friends
	☐	Live with other non-relatives (specify below)
	☐	Live in a group home
	☐	Other (please specify below)
F1a. If applicable, specify the other relative(s)		
F1b. If applicable, specify the other non-relative(s)		

Section G. ACCESS TO CARE
In the past year, have you avoided obtaining any of the following because of cost?

* G1. Medications	○	Yes
	○	No
	○	Unknown
	○	Decline to answer

* G2. Heart surgery	○ Yes ○ No ○ Unknown ○ Decline to answer
* G3. Heart catheterization or other heart procedures like pacemaker/ICD placement	○ Yes ○ No ○ Unknown ○ Decline to answer
* G4. A diagnostic test (like echocardiogram, CT scan, MRI, stress test, or Holter monitor)	○ Yes ○ No ○ Unknown ○ Decline to answer
* G5. An appointment with a cardiologist	○ Yes ○ No ○ Unknown ○ Decline to answer
* G6. An appointment with a primary care provider	○ Yes ○ No ○ Unknown ○ Decline to answer

Section H. COMBINED HOUSEHOLD INCOME

* H1. Combined household income (you and your household members) (check one)	○ Less than $25,000 ○ $25,000-49,000 ○ $50,000-74,999 ○ $75,000-99,999 ○ $100,000-149,999 ○ $150,000 or more ○ Do not wish to provide ○ Do not know
Section I. COVID-19 STATUS	
* I1. At any time have you tested positive for COVID-19 (also called SARS CoV-2) through a swab in your nose or a blood test (also called an antigen test)?	○ Yes ○ No ○ Unknown ○ Decline to answer
* I2. At any time have you tested positive for antibodies for COVID-19 (also called SARS CoV-2)? Antibody tests are a blood test that indicate if you may have had a COVID-19 infection in the past.	○ Yes ○ No ○ Unknown ○ Decline to answer
* I3. Have you recieved at least one vaccine shot for COVID-19 (also called SARS CoV-2)?	○ Yes ○ No ○ Unknown ○ Decline to answer

Psychiatric and Substance History

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 50 / Visit Display Name = Participant Forms / Visit Abbrev = PART / PageID = 30 / Page Display Name = Psychiatric and Substance History / Description = Psychiatric and Substance History ePRO version with decline to answer)

Section A. GENERAL INFORMATION		
A1. Date Form Completed:		(DD-MMM-YYYY)
A2. Time Form Completed:		(HH24:MI)
Section B: PSYCHIATRIC HISTORY		
* B1. Current diagnosis of Depression (within the last 3 months)	○ Yes ○ No ○ Decline to answer	
* B2. Past diagnosis of Depression	○ Yes ○ No ○ Decline to answer	
* B3. Current diagnosis of Anxiety (within the last 3 months)	○ Yes ○ No ○ Decline to answer	
* B4. Past diagnosis of Anxiety	○ Yes ○ No ○ Decline to answer	
* B5. Other current psychiatric history (within the last 3 months)	○ Yes ○ No ○ Decline to answer	
* B6. Other past psychiatric history	○ Yes ○ No ○ Decline to answer	

* B7. If applicable, please specify other psychiatric history:	

Section C. SUBSTANCE USE

If you have used any of the following, please specify below.

* C1. Current alcohol use (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* C1a. If yes, how often?	○ once a month or less ○ 2 to 4 times a month ○ 2 to 3 times a week ○ 4 or more times a week ○ Decline to answer
* C1b. When consuming alcohol, how many glasses do you have on average?	○ 1 to 2 ○ 3 to 4 ○ 5 to 6 ○ 7 to 9 ○ 10 or more ○ Decline to answer
* C1c. How often do you drink 6 glasses or more on occasion?	○ Never ○ Less than once a month ○ Monthly ○ Weekly ○ Daily or almost every day ○ Decline to answer
* C2. Past alcohol use	○ Yes ○ No ○ Decline to answer

* C3. Current marijuana use (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* C3a. If yes, how often?	○ once a month or less ○ 2 to 4 times a month ○ 2 to 3 times a week ○ 4 or more times a week ○ Decline to answer
* C4. Past marijuana use	○ Yes ○ No ○ Decline to answer
* C5. Current hashish use (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* C5a. If yes, how often?	○ once a month or less ○ 2 to 4 times a month ○ 2 to 3 times a week ○ 4 or more times a week ○ Decline to answer
* C6. Past hashish use	○ Yes ○ No ○ Decline to answer
* C7. Current heroin use (within the last 3 months)	○ Yes ○ No ○ Decline to answer

* C7a. If yes, how often?	○ once a month or less ○ 2 to 4 times a month ○ 2 to 3 times a week ○ 4 or more times a week ○ Decline to answer
* C8. Past heroin use	○ Yes ○ No ○ Decline to answer
* C9. Current use of other opioids (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* C9a. If yes, how often?	○ once a month or less ○ 2 to 4 times a month ○ 2 to 3 times a week ○ 4 or more times a week ○ Decline to answer
* C10. Past use of other opioids	○ Yes ○ No ○ Decline to answer
* C11. Current cocaine use (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* C11a. If yes, how often?	○ once a month or less ○ 2 to 4 times a month ○ 2 to 3 times a week ○ 4 or more times a week ○ Decline to answer

* C12. Past cocaine use	○ Yes ○ No ○ Decline to answer
* C13. Current use of a non-prescribed stimulant amphetamine (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* C13a. If yes, how often?	○ once a month or less ○ 2 to 4 times a month ○ 2 to 3 times a week ○ 4 or more times a week ○ Decline to answer
* C14. Past use of a non-prescribed stimulant amphetamine	○ Yes ○ No ○ Decline to answer
* C15. Current use of the stimulant methamphetamine for recreational use, not prescribed (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* C15a. If yes, how often?	○ once a month or less ○ 2 to 4 times a month ○ 2 to 3 times a week ○ 4 or more times a week ○ Decline to answer
* C16. Past use of the stimulant methamphetamine for recreational use, not prescribed	○ Yes ○ No ○ Decline to answer
* C17. Current use of methylenedioxymethamphetamine (ecstasy) (within the last 3 months)	○ Yes ○ No ○ Decline to answer

* C17a. If yes, how often?	○ once a month or less ○ 2 to 4 times a month ○ 2 to 3 times a week ○ 4 or more times a week ○ Decline to answer
* C18. Past use of methylenedioxymethamphetamine (ecstasy)	○ Yes ○ No ○ Decline to answer
* C19. Current use of phencyclidine (PCP) and analogues (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* C19a. If yes, how often?	○ once a month or less ○ 2 to 4 times a month ○ 2 to 3 times a week ○ 4 or more times a week ○ Decline to answer
* C20. Past use of phencyclidine (PCP) and analogues	○ Yes ○ No ○ Decline to answer
* C21. Current use of lysergic acid diethylamide (LSD or acid) (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* C21a. If yes, how often?	○ once a month or less ○ 2 to 4 times a month ○ 2 to 3 times a week ○ 4 or more times a week ○ Decline to answer

* C22. Past use of lysergic acid diethylamide (LSD or acid)	○ Yes ○ No ○ Decline to answer
* C23. Current use of inhalants (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* C23a. If yes, how often?	○ once a month or less ○ 2 to 4 times a month ○ 2 to 3 times a week ○ 4 or more times a week ○ Decline to answer
* C24. Past use of inhalants	○ Yes ○ No ○ Decline to answer
* C25. Current use of anabolic steroids (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* C25a. If yes, how often?	○ once a month or less ○ 2 to 4 times a month ○ 2 to 3 times a week ○ 4 or more times a week ○ Decline to answer
* C26. Past use of anabolic steroids	○ Yes ○ No ○ Decline to answer
* C27. Current use of another substance (within the last 3 months)	○ Yes ○ No ○ Decline to answer

* C27a. If yes, how often?	○ once a month or less ○ 2 to 4 times a month ○ 2 to 3 times a week ○ 4 or more times a week ○ Decline to answer
* C28. Past use of another substance	○ Yes ○ No ○ Decline to answer
* C29. If applicable, please specify other substance:	

Section D. TREATMENT FOR PSYCHIATRIC CONDITIONS AND SUBSTANCE USE

* D1. Current treatment with medication for depression (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* D2. Current counseling for depression (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* D3. Past treatment with medication for depression	○ Yes ○ No ○ Decline to answer
* D4. Past counseling for depression	○ Yes ○ No ○ Decline to answer
* D5. Current treatment with medication for anxiety (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* D6. Current counseling for anxiety (within the last 3 months)	○ Yes ○ No ○ Decline to answer

* D7. Past treatment with medication for anxiety	○ Yes ○ No ○ Decline to answer
* D8. Past counseling for anxiety	○ Yes ○ No ○ Decline to answer
* D9. Current treatment with medication for substance use (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* D10. Current counseling for substance use (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* D11. Past treatment with medication for substance use	○ Yes ○ No ○ Decline to answer
* D12. Past counseling for substance use	○ Yes ○ No ○ Decline to answer
* D13. Current treatment with medication for mental health or psychiatric condition (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* D14. Current counseling for another condition (within the last 3 months)	○ Yes ○ No ○ Decline to answer
* D15. Past treatment with medication for another condition	○ Yes ○ No ○ Decline to answer

* D16. Past Counseling for another condition	○ Yes ○ No ○ Decline to answer
* D17. If applicable, please list the other condition for which you received counseling and/or medication:	

Hospital Anxiety and Depression Scale (HADS)

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 50 / Visit Display Name = Participant Forms / Visit Abbrev = PART / PageID = 40 / Page Display Name = Hospital Anxiety and Depression Scale (HADS) / Description = HADS Questionnaire - SR)

Section A. GENERAL INFORMATION

A1. Date Form Completed:		(DD-MMM-YYYY)
A2. Time Form Completed:		(HH24:MI)

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

* I feel tense or 'wound up':	○ Most of the time ○ A lot of the time ○ From time to time, occasionally ○ Not at all
* I still enjoy the things I used to enjoy:	○ Definitely as much ○ Not quite so much ○ Only a little ○ Hardly at all
* I get a sort of frightened feeling as if something awful is about to happen:	○ Very definitely and quite badly ○ Yes, but not too badly ○ A little, but it doesn't worry me ○ Not at all
* I can laugh and see the funny side of things:	○ As much as I always could ○ Not quite so much now ○ Definitely not so much now ○ Not at all

* Worrying thoughts go through my mind:	○ A great deal of the time ○ A lot of the time ○ From time to time, but not too often ○ Only occasionally
* I feel cheerful:	○ Not at all ○ Not often ○ Sometimes ○ Most of the time
* I can sit at ease and feel relaxed:	○ Definitely ○ Usually ○ Not Often ○ Not at all
* I feel as if I am slowed down:	○ Nearly all the time ○ Very often ○ Sometimes ○ Not at all
* I get a sort of frightened feeling like 'butterflies' in the stomach:	○ Not at all ○ Occasionally ○ Quite Often ○ Very Often
* I have lost interest in my appearance:	○ Definitely ○ I don't take as much care as I should ○ I may not take quite as much care ○ I take just as much care as ever

* I feel restless as I have to be on the move:	○ Very much indeed ○ Quite a lot ○ Not very much ○ Not at all	
* I look forward with enjoyment to things:	○ As much as I ever did ○ Rather less than I used to ○ Definitely less than I used to ○ Hardly at all	
* I get sudden feelings of panic:	○ Very often indeed ○ Quite often ○ Not very often ○ Not at all	
* I can enjoy a good book or radio or TV program:	○ Often ○ Sometimes ○ Not often ○ Very seldom	
Total Score Depression (D)	(auto calculated)	(format xx)
Total Score Anxiety (A)	(auto calculated)	(format xx)

Adverse Event

Adverse Event Initial Report

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 60 (*) / Visit Display Name = Adverse Event / Visit Abbrev = AE / PageID = 10 / Page Display Name = Adverse Event Initial Report / Description = Adverse Event - Initial Report)

Section A. GENERAL INFORMATION		
* A1. Study ID Number		(format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.

For the purposes of this study, adverse events will include any untoward event that occurs to the participant during or within 24 hours of any study-related evaluation including completing the questionnaires, undergoing an interview, or collection of blood/saliva sample.

* A2. Adverse Event number		(format xx)
Section B. ADVERSE EVENT INFORMATION		
* B1. Adverse Event term		Please provide the Adverse Event term to best of knowledge.
* B2. Onset date		(DD-MMM-YYYY)Please provide the date that the Adverse Event first started.
* B3. Date site became aware of event		(DD-MMM-YYYY)Please provide the date that the Adverse Event was first noted.
* B4. Severity	○ Grade 1 - Mild ○ Grade 2 – Moderate ○ Grade 3 – Severe ○ Grade 4 – Life-threatening ○ Grade 5 – Death	
* B5. Causality related to study procedures	○ Not related ○ Possibly Related ○ Probably Related	

* B6. Is this event expected (nature or severity is consistent with information in the protocol or consent form)?	○ Yes ○ No	
Section C. TREATMENT/INTERVENTION STATUS		
* C1. Were any labs, tests, or studies done to diagnose/evaluate this event?	○ Yes ○ No	
Please upload de-identified source documents.		
* C2. Action taken	○ Yes ○ No	
* C2a. Medical Therapy (non-drug)	○ Yes ○ No	
* If yes, specify:		
* C2b. Number of Medications administered to treat AE?		(format xx)
Add medication information in the Medication visit pages for each medication administered to treat this AE.		
* C2c. Surgery/procedure performed to treat AE?	○ Yes ○ No	
* Number of surgeries performed		(format xx)
Please upload de-identified source documents.		
Section D. SAE		
* D1. Is this a Serious Adverse Event (SAE)?	○ Yes ○ No	SAE consists of events that are fatal or life threatening, results in death, requires or prolongs existing hospitalization, results in disability, or causes a congenital anomaly/birth defect.
* D1a. Resulted in death	○ Yes ○ No	

* How is this AE related to the cause of death?	○ PRIMARY ○ CONTRIBUTING ○ NOT RELATED ○ UNKNOWN	
* Date of death		(DD-MMM-YYYY)
* D1b. Immediately life-threatening event (immediate danger of death from event)	○ Yes ○ No	
* D1c. Requires hospitalization or prolongation of existing hospitalization	○ Yes ○ No	
* Hospitalization date		(DD-MMM-YYYY)
* Has the participant been discharged?	○ Yes ○ No	
* Discharge date		(DD-MMM-YYYY)
* D1d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions	○ Yes ○ No	
* D1e. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria	○ Yes ○ No	
Section E. OUTCOME & NARRATIVE		
* E1. Outcome	○ Ongoing ○ Resolved with sequelae ○ Resolved without sequelae ○ Ongoing at time of death	For "Ongoing" events, please complete a follow up form.
* E1a. Date of Resolution or Clinical Stability		(DD-MMM-YYYY)

* E2. Event Narrative (The physician narrative must consist of a clear, concise and accurate description of the event.)	

Adverse Event Follow Up

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 60 (*) / Visit Display Name = Adverse Event / Visit Abbrev = AE / PageID = 20 / Page Display Name = Adverse Event Follow Up / Description = Adverse Event - Follow Up)

Section A. GENERAL INFORMATION		
* A1. Study ID Number		(format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.
For the purposes of this study, adverse events will include any untoward event that occurs to the participant during or within 24 hours of any study-related evaluation including completing the questionnaires, undergoing an interview, or collection of blood/saliva sample.		
* A2. Adverse Event number		(format xx)
* A3. Did anything change since the initial form was completed?	○ Yes ○ No	
Section B. ADVERSE EVENT INFORMATION		
If nothing has changed, please skip to Section E.		
* B1. Adverse Event term		Please provide the Adverse Event term to best of knowledge.
* B2. Onset date		(DD-MMM-YYYY)Please provide the date that the Adverse Event first started.
* B3. Date site became aware of event		(DD-MMM-YYYY)Please provide the date that the Adverse Event was first noted.
* B4. Severity	○ Grade 1 - Mild ○ Grade 2 – Moderate ○ Grade 3 – Severe ○ Grade 4 – Life-threatening ○ Grade 5 – Death	
* B5. Causality related to study procedures	○ Not related ○ Possibly Related ○ Probably Related	

* B6. Is this event expected (nature or severity is consistent with information in the protocol or consent form)?	○ Yes ○ No	
Section C. TREATMENT/INTERVENTION STATUS		
* C1. Were any labs, tests, or studies done to diagnose/evaluate this event?	○ Yes ○ No	
Please upload de-identified source documents.		
* C2. Action taken	○ Yes ○ No	
* C2a. Medical Therapy (non-drug)	○ Yes ○ No	
* If yes, specify:		
* C2b. Number of Medications administered to treat AE?		(format xx)
Add medication information in the Medication visit pages for each medication administered to treat this AE.		
* C2c. Surgery/procedure performed to treat AE?	○ Yes ○ No	
* Number of surgeries performed		(format xx)
Please upload de-identified source documents.		
Section D. SAE		
* D1. Is this a Serious Adverse Event (SAE)?	○ Yes ○ No	SAE consists of events that are fatal or life threatening, results in death, requires or prolongs existing hospitalization, results in disability, or causes a congenital anomaly/birth defect.
* D1a. Resulted in death	○ Yes ○ No	

* How is this AE related to the cause of death?	○ PRIMARY ○ CONTRIBUTING ○ NOT RELATED ○ UNKNOWN	
* Date of death		(DD-MMM-YYYY)
* D1b. Immediately life-threatening event (immediate danger of death from event)	○ Yes ○ No	
* D1c. Requires hospitalization or prolongation of existing hospitalization	○ Yes ○ No	
* Hospitalization date		(DD-MMM-YYYY)
* Has the participant been discharged?	○ Yes ○ No	
* Discharge date		(DD-MMM-YYYY)
* D1d. Results in persistent or significant incapability or substantial disruption of the ability to conduct normal life functions	○ Yes ○ No	
* D1e. Important Medical Event: Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria	○ Yes ○ No	

Section E. OUTCOME & NARRATIVE

* E1. Outcome	○ Ongoing ○ Resolved with sequelae ○ Resolved without sequelae ○ Ongoing at time of death	
* E1a. Date of Resolution or Clinical Stability		(DD-MMM-YYYY)

* E2. Event Narrative (The physician narrative must consist of a clear, concise and accurate description of the event.)	

Protocol Deviation

Protocol Deviation

[Revision: MSU 3 - protocol amendment 5 (new inclusion/exclusion)]

(Visit ID = 70 / Visit Display Name = Protocol Deviation / Visit Abbrev = PD / PageID = 10 (*) / Page Display Name = Protocol Deviation / Description = Protocol Deviation)

Section A. GENERAL INFORMATION		
* A1. Study ID Number		(format xxxxxx) Participant ID must match the ID on the Pre-Screening Form.
Section B: PROTOCOL DEVIATION		
Instructions: Please complete a new form for each Protocol Deviation.		
* B1. Date of protocol deviation		(DD-MMM-YYYY)
* B2. Please select type of protocol deviation (if applicable) and explain in more detail below:	○ ICF not signed/Dated appropriately ○ One or more of the inclusion/exclusion criteria was not met ○ Assessment/Procedure not completed ○ Assessment/Procedure done incorrectly ○ Adverse events not reported within protocol defined time frame ○ Other (please describe below)	

* B3. Please select all the inclusion/exclusion criteria that were not met:	☐ Inclusion: Age 18-30 years ☐ Inclusion: CHD (repaired or unrepaired) of moderate or severe complexity ☐ Exclusion: CHD of mild complexity ☐ Exclusion: Heart disease that is not classified as structural CHD ☐ Exclusion: Inability to complete the surveys or testing ☐ Exclusion: Prior completion of the NIH Toolbox Cognitive Battery at any time
* B4. Please select all assessments not completed:	☐ NIH Toolbox Cognitive Battery ☐ NeuroQOL Item Bank v2.0 Cognitive Function ☐ Hospital Anxiety and Depression Scale (HADS) ☐ PROMIS Scale v1.2 Global Health ☐ Demographic information (some or all) ☐ Clinical/Medical information (some or all) ☐ Biospecimen
* B4a. If applicable, please explain why the biospecimen was not collected. Please keep in mind that if the participant declined to provide a sample or withdrew, this is not a protocol deviation	○ Participant agreed to provide biospecimen but biospecimen was not collected ○ Site attempted, but was unable to collect adequate biospecimen ○ Other

* B5. Please select all assessments that were not completed correctly per protocol	☐ NIH Toolbox Cognitive Battery ☐ NeuroQOL Item Bank v2.0 Cognitive Function ☐ Hospital Anxiety and Depression Scale (HADS) ☐ PROMIS Scale v1.2 Global Health ☐ Demographic information (some or all) ☐ Clinical/Medical information (some or all) ☐ Biospecimen
* B6. Please provide additional details regarding the deviation	