National Institutes of Health
National Institute of Neurological Disorders and Stroke
National Institute on Aging

MarkVCID Paper Case Report Form Initial Completion Guidelines

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MarkVCID Consortium

By the MarkVCID Clinical Data, Physiological Data & Cognitive Assessments Subcommittee (Deborah Blacker, MD, ScD, Chair) and Coordinating Center (PI Steven Greenberg, MD, PhD).

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MarkVCID Paper CRF Completion Guidelines

Contents

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

DEMOGRAPHICS AND RELATED ELEMENTS
Date of Birth: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY) **NOTE: DOB is only entered in the registration form and used to calculate the age. DOB is not saved in the data system**
Date of Collection: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)
1. Sex: ☐ Male ☐ Female
2. Does the subject report being of Hispanic/Latino ethnicity (i.e., having origins from a mainly Spanish-speaking Latin American country), regardless of race? ☐ No ☐ Yes ☐ Unknown
Ask the subject (or co-participant, if necessary) whether the subject considers her/his ethnicity to be Hispanic/Latino

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
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2a. If yes, what are the subject's reported origins?

- ☐ Mexican, Chicano, or Mexican-American
- ☐ Puerto Rican
- ☐ Cuban
- ☐ Dominican
- ☐ Central American
- ☐ South American
- ☐ Other (specify): _____
- ☐ Unknown

Ask the subject (or co-participant, if necessary) what s/he considers the subject's Hispanic origins to be. Read or show the choices, if required, and allow only one category choice.

*Select **Mexican, Chicano, or Mexican-American** if the subject reports having origins in Mexico.*

*Select **Puerto Rican** if the subject reports having origins in Puerto Rico.*

*Select **Cuban** if the subject reports having origins in Cuba.*

*Select **Dominican** if the subject reports having origins in the Dominican Republic.*

*Select **Central American** if the subject reports having origins in Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, or Panama.*

*Select **South American** if the subject reports having origins in Argentina, Bolivia, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay, or Venezuela.*

*Select **Other (specify)** if the subject reports origins other than those listed in the options above and enter the origin in the space provided.*

*Select **Unknown** only if the subject or co-participant is unable or unwilling to identify the subject's origins.*

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

3. What does the subject report as his or her race?

- ☐ White
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or other Pacific Islander
- ☐ Asian
- ☐ Other (specify): _____
- ☐ Unknown

Ask the subject (or, if necessary, the co-participant) what s/he considers the subject's race to be. NIH defines race and Hispanic ethnicity separately; therefore, please do not enter "Hispanic" or the subject's specific Hispanic origins (e.g., Mexico) as the subject's race. Instead, be sure to indicate Hispanic ethnicity in the previous question. If the subject will not identify a race and identifies only as Hispanic, select ***Unknown****. Read or show the choices and allow only one category choice. There will be an opportunity to record other applicable race categories in the following two questions.*

Native Hawaiian or other Pacific Islander *includes Native Hawaiian, Guamanian or Chamorro, Samoan, or other Pacific Islander.*

Asian *includes Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, or other Asian.*

If you select ***Other (specify)****, specify if the subject reports a race other than those listed above, and enter the race in the space provided. If the subject prefers to report her/his race as multiracial, select* ***Other (specify)****, and specify "multiracial".*

Select ***Unknown*** *only if the subject or co-participant is unable or unwilling to identify the subject's race.*

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

4. What additional race does the subject report?

- ☐ White
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or other Pacific Islander
- ☐ Asian
- ☐ Other (specify): _____
- ☐ None reported
- ☐ Unknown

If the subject or co-participant reports an additional race for the subject, select the box that corresponds to this additional race. Do not record a race that was already provided in the previous question.

Native Hawaiian or other Pacific Islander *and* ***Asian****: See inclusion list for previous question.*

Select ***Other (specify)*** *if the subject or co-participant reports an additional race other than those listed above and enter the race in the space provided.*

Select ***None reported*** *if the subject or co-participant reports no additional race for the subject beyond what was reported in the previous question.*

Select ***Unknown*** *if the subject or co-participant reports the subject as having an additional race but is unable or unwilling to identify it.*

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

5. What additional race, beyond those reported above, does the subject report?

- ☐ White
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or other Pacific Islander
- ☐ Asian
- ☐ Other (specify): _____
- ☐ None reported
- ☐ Unknown

If the subject or co-participant reports an additional race for the subject, select the box that corresponds to this additional race. Do not record a race that was already provided in the previous two questions.

Native Hawaiian or other Pacific Islander *and* ***Asian****: See inclusion list for previous questions.*

Select ***Other (specify)*** *if the subject or co-participant reports an additional race other than those listed above and enter the race in the space provided.*

Select ***None reported*** *if the subject or co-participant reports no additional race for the subject beyond what was reported in the previous two questions.*

Select ***Unknown*** *if the subject or co-participant reports the subject as having an additional race but is unable or unwilling to identify it.*

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

6. Subject's primary language:

- ☐ English
- ☐ Spanish
- ☐ Mandarin
- ☐ Cantonese
- ☐ Russian
- ☐ Japanese
- ☐ Other primary language (specify): _____
- ☐ Unknown

Record the language that the subject (or co-participant) considers to be the subject's main language — i.e., the language that s/he speaks and writes best.

*Select **Other primary language (specify)** if the subject or co-participant reports a primary language other than those described, and enter the language in the space provided.*

*Select **Unknown** only if the subject or co-participant is unable or unwilling to identify the subject's primary language.*

6b. If English is not the subject's primary language, is the subject fluent in English?

☐ No ☐ Yes ☐ Unknown

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

7. Is the subject left- or right-handed (for example, which hand would s/he normally use to write or throw a ball)?

☐ Left-handed

☐ Right-handed

☐ Ambidextrous

☐ Unknown

Select the box for the category that reflects the hand(s) used most predominantly by the subject, as indicated by the subject or co-participant.

*Select **Unknown** only if the subject or co-participant is unable or unwilling to identify the subject's handedness.*

8. Subject's current marital status:

☐ Married ☐ Never married (or marriage was annulled)

☐ Widowed ☐ Living as married/domestic partner

☐ Divorced ☐ Unknown

☐ Separated

Select the box for the category that most accurately describes the subject's current marital status.

***Living as married** may be applied to either heterosexual or same-sex relationships.*

*Select **Unknown** only if the subject or co-participant is unable or unwilling to identify the subject's marital status.*

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

9. What is the subject's living situation?

- ☐ Lives alone
- ☐ Lives with one other person: a spouse or partner
- ☐ Lives with one other person: a relative, friend, or roommate
- ☐ Lives with caregiver who is not spouse/partner, relative, or friend
- ☐ Lives with a group (related or not related) in a private residence
- ☐ Lives in group home (e.g., assisted living, nursing home, convent)
- ☐ Unknown

Select the box for the category most accurately describes the subject's current living situation.

*Select **Unknown** only if the subject or co-participant is unable or unwilling to identify the subject's living situation.*

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

10. What is the subject's level of independence?

- ☐ Able to live independently
- ☐ Requires some assistance with complex activities
- ☐ Requires some assistance with basic activities
- ☐ Completely dependent
- ☐ Unknown

Select the box for the category that most accurately describes the level of activity the subject is able to do. If the subject or co-participant indicates that the subject is able to perform complex activities but is not doing the activities because of her/his living situation, the subject is still considered to be able to live independently.

*Select **Requires some assistance with complex activities** if subject has deterioration in accustomed complex abilities (e.g., paying bills, shopping, remembering appointments, driving, cooking).*

*Select **Requires some assistance with basic activities** if subject has deterioration in accustomed basic abilities (e.g., eating, dressing, personal hygiene).*

*Select **Completely dependent** if subject is unable to perform basic activities of daily living.*

*Select **Unknown** only if the subject or co-participant is unable or unwilling to identify the subject's living situation.*

11. ZIP Code (first three digits) of subject's primary residence: ___ ___ ___ ☐ Unknown

*Provide the first three digits of the subject's ZIP Code. If the ZIP Code is unknown, select **Unknown** checkbox.*

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ___ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

12. Occupation during most of working career:

Occupation Category Number: _____

Occupation: _____

If other, specify: _____

Using the Hollingshead Index found in the appendix, first identify the category (1-7) of the subject's occupation, based on their skill level and experience. Then, within that category, select the occupation that most closely corresponds to the subject's reported occupation. If a suitable occupation is not listed, select the ***If Other, specify*** *option within the appropriate category, and record the occupation in the space provided.*

13. Subject's years of education — use the codes below to report the level achieved; if an attempted level is not completed, enter the number of years completed: ___ ___ ☐ Unknown

(12 = high school or GED, 16 = bachelor's degree, 18 = master's degree, 20 = doctorate)

This question refers to achieved educational levels, rather than the number of years it took to complete that level. Use the following to describe achieved educational levels: High school or GED = 12 years, bachelor's degree = 16 years, master's degree = 18 years, doctorate = 20 years.

If the subject has not completed a level, enter the total number of years of education completed toward that level.

Examples: If the subject attended school for eight years and did not earn a diploma or GED, enter "08". If the subject completed 17.5 years of school and earned a bachelor's degree but did not complete an attempted master's degree, enter "17". (However, if the subject attended school for 17.5 years to earn a bachelor's degree and that was the intended level of achievement, then enter "16".) If the subject attended school for 25 years to earn a PhD, enter "20" to indicate the achieved educational level.

If the subject or co-participant is unable or unwilling to answer the question, select the checkbox for 'Unknown.'

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

MEDICAL/NEUROLOGICAL/PSYCHIATRIC HISTORY

Date of Collection: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)

HISTORY OF CIGARETTE SMOKING

	No	Yes	Unknown
1. Has the subject smoked within the last 30 days?	☐	☐	☐
2. Has the subject smoked more than 100 cigarettes in her/his life?	☐	☐	☐

*If **No** or **Unknown**, skip to **Cardiovascular Disease** section*

2a. Total years smoked: ___ ___ [0-87] ☐ Unknown

*If the exact number of years smoked is unknown, ask the subject and/or co-participant to estimate. If he/she cannot estimate, select **Unknown** checkbox.*

2b. Average number of packs smoked per day:

- ☐ 1 cigarette to less than ½ pack
- ☐ ½ pack to less than 1 pack
- ☐ 1 pack to less than 1½ packs
- ☐ 1½ packs to less than 2 packs
- ☐ 2 packs or more
- ☐ Unknown

2c. If the subject has quit smoking, specify that age at which he/she last smoked (i.e., quit): ___ ___ ___ [8-110] ☐ N/A ☐ Unknown

*If the exact age is unknown, ask the subject and/or co-participant to estimate. If he/she still smokes, select **N/A**. If he/she cannot estimate, select **Unknown** checkbox.*

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials: ____ ____ ____**
Visit Date: ____ ____/ ____ ____/ ____ ___ ____ ____	**Evaluator Initials: ____ ____ ____**
Study Visit:	

*For the sections below, record the presence or absence of a **history** of these conditions **at this visit**, as determined by the clinician's best judgment following the medical history interview with the subject and informant.*

A condition should be considered….

- ***Absent*** *IF* *… it is not indicated by information obtained from the subject and co-participant interview.*
- ***Recent/ active*** *IF* *… it happened within the last year or still requires active management and is consistent with information obtained from the subject and co-participant interview.*
- ***Remote/ inactive*** *IF* *… it existed or occurred in the past (more than one year ago) but was resolved or there is no treatment currently under way.*
- ***Unknown*** *IF* *… there is insufficient information available from the subject and co-participant interview.*

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

CARDIOVASCULAR DISEASE	Absent	Recent/active	Remote/inactive	Unknown
1. Heart attack/cardiac arrest	☐	☐	☐	☐
If not Absent or Unknown:				
1a. More than one heart attack? ☐ No ☐ Yes ☐ Unknown				
1b. Age at most recent heart attack: __ __ ☐ Unknown				
*If the exact age is unknown, ask the subject and/or co-participant to estimate. If he/she cannot estimate, select **Unknown** checkbox.*				
	Absent	Recent/active	Remote/inactive	Unknown
2. Atrial fibrillation	☐	☐	☐	☐
3. Angioplasty/ endarterectomy/ stent	☐	☐	☐	☐
4. Cardiac bypass procedure	☐	☐	☐	☐
5. Pacemaker and/or defibrillator	☐	☐	☐	☐
6. Congestive heart failure	☐	☐	☐	☐
7. Angina	☐	☐	☐	☐
8. Heart valve replacement or repair	☐	☐	☐	☐

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

*For Questions 9-11, ask whether the subject has any cardiovascular disease other than those listed in Questions 1-8. If no, select **Absent**. If yes, record the condition in the space provided and select the appropriate box to specify whether **Recent/ active** or **Remote/ inactive**.*

	Absent	Recent/active	Remote/inactive	Unknown
9. Other cardiovascular disease (specify): (enter 'N/A' if absent) _____	☐	☐	☐	☐
10. Other cardiovascular disease (specify): (enter 'N/A' if absent) _____	☐	☐	☐	☐
11. Other cardiovascular disease (specify): (enter 'N/A' if absent) _____	☐	☐	☐	☐

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ___ ___/ ___ ___/ ___ __ ___ ___	**Evaluator Initials:** ____ ____ ____
Study Visit:	

CEREBROVASCULAR HISTORY

History of Symptomatic Stroke/ Acute Vascular Event?
☐ No ☐ Yes ☐ Unknown

This question is focused on reported history of stroke. Include stroke reported during the interview with the subject and/or co-participant. Imaging evidence of a stroke or evidence from a physical exam are not required as this question is focused on reported history. For 'Age at Event', if the exact age is unknown, ask the subject and/or co-participant to estimate. If s/he cannot estimate, select ***Unknown*** *checkbox. To answer whether the event is temporally associated with persistent worsening of cognition, temporal relationship is defined in two ways: either 1) when the event occurred, there was a stepwise decline in cognition; or 2) the event was followed by cognitive decline noted within three to six months. Select* ***Yes*** *if either of these two conditions is present. Select* ***No*** *if there is a no history of cognitive decline within six months of the event.*

If yes, complete the following:

Event	Age at Event	Type of Symptomatic Stroke/Acute Vascular Event	Temporally associated with persistent worsening of cognition?
Stroke/Acute Vascular Event 1	— — ☐Unknown	☐ Ischemic ☐ Hemorrhagic ☐ Stroke type unknown ☐ TIA with clear ischemic mechanism	☐ No ☐ Yes ☐ Unknown
Stroke/Acute Vascular Event 2	— — ☐Unknown	☐ Ischemic ☐ Hemorrhagic ☐ Stroke type unknown ☐ TIA with clear ischemic mechanism	☐ No ☐ Yes ☐ Unknown
Stroke/Acute Vascular Event 3	— — ☐Unknown	☐ Ischemic ☐ Hemorrhagic ☐ Stroke type unknown ☐ TIA with clear ischemic mechanism	☐ No ☐ Yes ☐ Unknown
Stroke/Acute Vascular Event 4	— — ☐Unknown	☐ Ischemic ☐ Hemorrhagic ☐ Stroke type unknown ☐ TIA with clear ischemic mechanism	☐ No ☐ Yes ☐ Unknown
Stroke/Acute Vascular Event 5	— — ☐Unknown	☐ Ischemic ☐ Hemorrhagic ☐ Stroke type unknown ☐ TIA with clear ischemic mechanism	☐ No ☐ Yes ☐ Unknown

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

NEUROLOGIC CONDITIONS				
Condition	Absent	Recent/active	Remote/inactive	Unknown
1. Seizures	☐	☐	☐	☐
2. Traumatic brain injury (TBI)	☐	☐	☐	☐
Include any reported TBI, including mild TBI and TBI without loss of consciousness				
If TBI recent/active or remote/inactive:				
2a. TBI with brief loss of consciousness (< 5 minutes) ☐ No ☐ Single ☐ Repeated/multiple ☐ Unknown				
2b. TBI with extended loss of consciousness (≥ 5 minutes) ☐ No ☐ Single ☐ Repeated/multiple ☐ Unknown				
2c. TBI without loss of consciousness (as might result from military detonations or sports injuries)? ☐ No ☐ Single ☐ Repeated/multiple ☐ Unknown				
*If the subject has experienced multiple TBIs with loss of consciousness, but the amount of time unconscious is unknown for all instances, select **Unknown** for Questions 2a and 2b. If for any of questions 2a, 2b, or 2c, the subject knows there has definitely been at least a single instance, but is unsure whether there has been more than one, select **Single**, and revise the entry on this form to **Repeated/multiple** at a future date if more specific information is available at a future date.*				
2d. Age at most recent TBI: ___ ___ ☐ Unknown				
*If exact age is unknown, ask the subject and/or co-participant to estimate. If he/she cannot estimate, select **Unknown** checkbox.*				

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

MEDICAL CONDITIONS

If any of the conditions still require active management and/or medications, please select "Recent/active."

Condition	Absent	Recent/active	Remote/inactive	Unknown
1. Diabetes	☐	☐	☐	☐

1a. If recent/active or remote/inactive, which type?
☐ Type 1 ☐ Type 2
☐ Other type (diabetes insipidus, latent autoimmune diabetes/ type 1.5, gestational diabetes) ☐ Unknown

1b. Age of onset: ___ ___ ☐ Unknown

Subject's estimated age at diagnosis. If subject cannot recall age at diagnosis, note age at first treatment.

2. Hypertension	☐	☐	☐	☐

Should be coded based on clinician's best judgment from review of medical records including medication use history and record of measured blood pressures, research subject interview, and blood pressure measurement at the research visit.
If there is no clear diagnosis of hypertension based on the history and record review, it is suggested that a diagnosis of HTN be considered if the person has had recent consistent readings of systolic BP of 140 mm Hg or above documented on at least 2 occasions. If there is no clear decision based on the history and record review and a diagnosis of HTN is being considered solely on the basis of the recorded BP at that visit, it is suggested that the subject should have an average measured systolic BP of 140 mm Hg or over or average measured diastolic BP of 90 mm Hg or above at the research visit (average of 3 consecutive BP measurements).

2a. If recent/active or remote/inactive, is hypertension treated?
☐ No ☐ Yes

2b. Age of onset: ___ ___ ☐ Unknown

Subject's estimated age at diagnosis. If subject cannot recall age at diagnosis, note age at first treatment.

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Condition	Absent	Recent/active	Remote/inactive	Unknown
3. Hypercholesterolemia	☐	☐	☐	☐
3a. Age of onset: ___ ___ ☐ Unknown				
Subject's estimated age at diagnosis. If subject cannot recall age at diagnosis, note age at first treatment.				
4. B12 deficiency	☐	☐	☐	☐
5. Thyroid disease	☐	☐	☐	☐
6. Arthritis	☐	☐	☐	☐
If recent/active or remote/inactive:				
6a. Type of arthritis: ☐ Rheumatoid ☐ Osteoarthritis ☐ Other (specify): _____ ☐ Unknown				
*If subject has both rheumatoid arthritis and osteoarthritis, select **Rheumatoid**.*				
6b. Region(s) affected (check all that apply): ☐ Upper extremity ☐ Lower extremity ☐ Spine ☐ Unknown				
7. Incontinence – urinary	☐	☐	☐	☐
8. Incontinence – bowel	☐	☐	☐	☐
9. Sleep apnea	☐	☐	☐	☐
9a. Age of onset: ___ ___ ☐ Unknown				
Subject's estimated age at diagnosis. If subject cannot recall age at diagnosis, note age at first treatment.				
10. REM sleep behavior disorder (RBD)	☐	☐	☐	☐
11. Hyposomnia/insomnia	☐	☐	☐	☐

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

SUBSTANCE ABUSE				
Substance Abuse	Absent	Recent/active	Remote/inactive	Unknown
1. Alcohol abuse: clinically significant impairment occurring over a 12-month period manifested in one of the following areas: work, driving, legal, or social	☐	☐	☐	☐
2. Other abused substances: clinically significant impairment occurring over a 12-month period manifested in one of the following areas: work, driving, legal, or social	☐	☐	☐	☐
2a. If recent/active or remote/inactive, specify abused substance: _____ _____				
*If multiple substances other than alcohol were used in the past, and at least one of the substances was used in the last 12 months, and it resulted in impairment in work, driving, legal, or social situations, select **Recent/active** and describe the abused substances in the space provided. If multiple substances were used but not within the past 12 months, select **Remote/inactive** and describe the substances in the space provided.*				

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

PSYCHIATRIC CONDITIONS, DIAGNOSED OR TREATED BY A PHYSICIAN				
Psychiatric Condition	Absent	Recent/active	Remote/inactive	Unknown
1. Post-traumatic stress disorder (PTSD)	☐	☐	☐	☐
During the interview, confirm with the subject and/or co-participant that the reported history of PTSD was based on a diagnosis or treatment by a physician/clinician.				
2. Bipolar disorder	☐	☐	☐	☐
During the interview, confirm with the subject and/or co-participant that the reported history of bipolar disorder was based on a diagnosis or treatment by a physician/clinician.				
3. Schizophrenia	☐	☐	☐	☐
During the interview, confirm with the subject and/or co-participant that the reported history of schizophrenia was based on a diagnosis or treatment by a physician/clinician.				
4. Depression				
4a. Active depression in the last two years ☐ No ☐ Yes ☐ Unknown				
4b. Depression episodes more than two years ago ☐ No ☐ Yes ☐ Unknown				
During the interview, confirm with the subject and/or informant that the reported history of depression was based on a diagnosis and/or treatment by a physician/clinician.				

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

	Absent	Recent/active	Remote/inactive	Unknown
5. Anxiety	☐	☐	☐	☐
6. Obsessive-compulsive disorder (OCD)	☐	☐	☐	☐
7. Developmental neuropsychiatric disorders (e.g., autism spectrum disorder [ASD], attention-deficit hyperactivity disorder [ADHD], dyslexia)	☐	☐	☐	☐
8. Other psychiatric disorders	☐	☐	☐	☐

8a. If recent/active or remote/inactive, specify disorder: _____

_____

*Ask whether the subject has any psychiatric disorder other than those listed in Questions 1–7. If no, select **Absent**. If yes, record the condition in the space provided and select the appropriate box to specify whether **Recent/active** or **Remote/inactive**.*

MEDICAL HISTORY

1. Does the subject ever cry or laugh apparently involuntarily, spontaneously, or out-of-proportion to the situation?
   - ☐ No
   - ☐ Yes
   - ☐ Unknown

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

FAMILY HISTORY			
Date of Collection: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)			
FAMILY HISTORY	No	Yes	Unknown
1. STROKE/TIA: Is there a family history in a first degree relative of symptomatic stroke or TIA with clear ischemic mechanism?	☐	☐	☐
*Select **Yes** if there are biological parents, full siblings, or biological children who have a history of symptomatic stroke and/or TIA with clear ischemic mechanism*			
If yes:			
1a. Any cases with onset before age 55?	☐	☐	☐
1b. Is there a pattern suggestive of an autosomal dominant family history?	☐	☐	☐
*Select **Yes** if history of stroke and/or TIA with clear ischemic mechanism appears in every known generation of one side of the family (e.g., mother's family or father's family)*			
2. ACQUIRED COGNITIVE IMPAIRMENT: Is there a family history in a first degree relative of cognitive impairment or dementia or Alzheimer's disease?	☐	☐	☐
*Select **Yes** if there are biological parents, full siblings, or biological children who are affected by dementia, Alzheimer's disease, or have history of cognitive impairment*			

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

	No	Yes	Unknown
If yes:			
2a. Any report of a case in the family with autopsy confirmation of Alzheimer's disease?	☐	☐	☐
2b. Any report of cases with autopsy confirmation of another cause of dementia?	☐	☐	☐
2c. Any cases with onset before age 65?	☐	☐	☐
2d. Is there a pattern suggestive of an autosomal dominant family history?	☐	☐	☐

*Select **Yes** if history of acquired cognitive impairment appears in every known generation of one side of the family (e.g., mother's family or father's family)*

3. **If yes** to EITHER autosomal dominant questions above (1b, 2d), complete the following:

3a. Is there a known mutation?

☐ No ☐ Yes

3b. If yes, please indicate which one:

☐ PSEN1

☐ APP

☐ PSEN2

☐ CADASIL

☐ Other, specify gene if known: _____

Specify mutation if known: _____

Although blood relatives might have evidence for more than one genetic mutation, indicate the predominant mutation only. Evidence may be provided via family report, test, or other report or documentation.
*First, specify the gene. Then, indicate the mutation, if known. If the gene is not listed, select **Other** and specify the gene.*

3c. Does this individual carry the mutation?

☐ No ☐ Yes ☐ Unknown

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

GENERAL PHYSICAL MEASURES

Were General Physical Measures performed? ☐ No ☐ Yes

If No, please provide the primary reason:

☐ Physical problem ☐ Verbal refusal

☐ Cognitive/behavior problem ☐ Other problem (specify): _____

_____

Date of Collection: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)

VITAL SIGNS

1. Blood Pressure Measurement 1: ___ ___ ___ / ___ ___ ___ mmHg ☐ Not Done

   Blood Pressure Measurement 2: ___ ___ ___ / ___ ___ ___ mmHg ☐ Not Done

   Blood Pressure Measurement 3: ___ ___ ___ / ___ ___ ___ mmHg ☐ Not Done

Measure seated at rest. Take 3 consecutive BP readings. Average will be calculated in EDC. If blood pressure cannot be obtained, skip and select 'Not Done' in the EDC.

2. Pulse: ___ ___ ___ beats/minute ☐ Not Done

If pulse cannot be obtained, skip and select 'Not Done' in the EDC.

3. Height: ___ ___ ___ . ___ ☐ cm ☐ in ☐ Not Done

If height cannot be measured (e.g., if subject is confined to a wheelchair or unable to stand), skip and select 'Not Done' in the EDC.

4. Weight: ___ ___ ___ . ___ ☐ kg ☐ lb ☐ Not Done

If weight cannot be measured (e.g., if subject is confined to a wheelchair or unable to stand), skip and select 'Not Done' in the EDC.

ADDITIONAL PHYSICAL OBSERVATIONS	No	Yes	Unknown
1. With or without corrective lenses, is the subject's vision functionally normal?	☐	☐	☐
*Select **No** if any functional impairment exists (reduced ability to do everyday activities such as reading or watching television).*			
2. With or without a hearing aid(s), is the subject's hearing functionally normal?	☐	☐	☐

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

*Select **No** if any functional impairment exists (reduced ability to do everyday activities such as listening to the radio or television, talking with family or friends).*

SHORT PHYSICAL PERFORMANCE BATTERY	
Please refer to the MarkVCID Short Physical Performance Battery Training Manual for detailed instructions on the administration of this assessment.	
KEY: If the subject cannot complete any of the following exams, please give the reason by entering one of the following codes: 95 = Physical problem 96 = Cognitive/behavior problem 97 = Other problem 98 = Verbal refusal	
1. Balance Test Score: *Side-by-side, semi-tandem, tandem*:	___ ___ [0-4, 95-98]
2. Gait Speed Test Score:	___ ___ [0-4, 95-98]
3. Chair Stand Test Score:	___ ___ [0-4, 95-98]

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

NEUROLOGICAL EXAM

INSTRUCTIONS: This form must be completed by a clinician with experience in assessing the neurological signs listed below and in attributing the observed findings to a particular syndrome. Please use your best clinical judgment in assigning the syndrome.

Use the information obtained at the neurological exam to indicate the neurological findings, using your best clinical judgment to ascribe those symptoms to a particular clinical syndrome.

Please complete the appropriate sections below, using your best clinical judgment in selecting findings that indicate the likely syndrome(s) that is/are present.

Was the Neurological Exam performed?

☐ No ☐ Yes

If No, please provide the primary reason:

☐ Physical problem ☐ Verbal refusal

☐ Cognitive/behavior problem ☐ Other problem (specify): _____

_____

Date of Collection: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

PARKINSONIAN FEATURES			
Were Parkinsonian signs present? ☐ No ☐ Yes			
*If any of the parkinsonian signs listed below are present, select **Yes**. Otherwise, select **No** and skip to **Cerebrovascular Features** section*			
Parkinsonian Signs: **LEFT**	No	Yes	Not Assessed
1. Resting tremor – arm	☐	☐	☐
*A definite rest tremor, even if only intermittent, is sufficient to select **Yes**.*			
2. Slowing of fine motor movements	☐	☐	☐
*This refers to movements such as finger tapping, hand pronation-supination, or foot- or toe-tapping. Significant slowing, even if slight or mild, is sufficient to select **Yes**.*			
3. Rigidity - arm	☐	☐	☐
*Rigidity should be judged on passive movement of major joints with patient relaxed in sitting position; cogwheeling and paratonia (gegenhalten) to be ignored. Any degree of rigidity is sufficient to select **Yes**.*			
Parkinsonian Signs: **RIGHT**	No	Yes	Not Assessed
4. Resting tremor – arm	☐	☐	☐
*A definite rest tremor, even if only intermittent, is sufficient to select **Yes**.*			
5. Slowing of fine motor movements	☐	☐	☐
*This refers to movements such as finger tapping, hand pronation-supination, or foot- or toe-tapping. Significant slowing, even if slight or mild, is sufficient to select **Yes**.*			
6. Rigidity - arm	☐	☐	☐
*Rigidity should be judged on passive movement of major joints with patient relaxed in sitting position; cogwheeling and paratonia (gegenhalten) to be ignored. Any degree of rigidity is sufficient to select **Yes**.*			

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Parkinsonian Signs	No	Yes	Not Assessed
7. Bradykinesia	☐	☐	☐
*Bradykinesia includes combining slowness, hesitancy, decreased arm swing, small amplitude, and poverty of movement in general. Any degree of overall bradykinesia is sufficient to select **Yes**.*			
8. Parkinsonian gait disorder	☐	☐	☐
*Features of parkinsonian gait disorder include slowing of gait, shuffling, festination, unilateral or bilateral decreased arm swing and/or tremor, slowness and difficulty on turning, and/or freezing during walking. Any degree of parkinsonian gait is sufficient to select **Yes**.*			
9. Postural instability	☐	☐	☐
*Postural instability involves inadequate response to sudden, strong posterior displacement produced by pull on shoulders while patient is erect with eyes open and feet slightly apart; patient is prepared. Taking more than two steps or requiring the examiner to catch the subject are examples of postural instability. Any degree of postural instability is sufficient to select **Yes.***			

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

CEREBROVASCULAR FEATURES			
Were neurological signs considered by examiner to be most likely consistent with cerebrovascular disease present? ☐ No ☐ Yes			
*If any of the signs consistent with CVD below are present, select **Yes**; otherwise, select **No** and skip to **Other Findings** section.*			
Findings consistent with stroke / cerebrovascular disease	No	Yes	Not Assessed
1. Cortical cognitive deficit (e.g., aphasia, apraxia, neglect)	☐	☐	☐
***Aphasia**: Difficulty with language, including impaired word retrieval or naming.* ***Apraxia**: Difficulty in correctly carrying out purposeful skilled movements in the absence of motor or sensory loss.* ***Neglect**: Lack of awareness of entire sectors of space or one side of the body.*			
Findings consistent with stroke / cerebrovascular disease: **LEFT SIDE OF BODY**	No	Yes	Not Assessed
2. Lateralized motor weakness	☐	☐	☐
Indicate as present if it is suspected that there is acquired proximal or distal extremity weakness attributable to cerebrovascular ischemia.			
3. Lateralized abnormal reflexes (to include pathologically brisk deep tendon reflexes, Babinski signs, others)	☐	☐	☐
Indicate as present if it is suspected that there are brisk reflexes or increased tone attributable to cerebrovascular ischemia.			
4. Cortical visual field loss	☐	☐	☐
This involves homonymous hemianopsia or quadrantanopsia, or cortical blindness, excluding visual field loss due to optic nerve disease or injury.			
5. Somatosensory loss	☐	☐	☐
This involves sensory loss due to involvement of the cerebrum or brain stem, excluding sensory loss due to spinal-cord injury or peripheral neuropathy.			

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Findings consistent with stroke / cerebrovascular disease: **RIGHT SIDE OF BODY**	No	Yes	Not Assessed
6. Lateralized motor weakness	☐	☐	☐
Indicate as present if it is suspected that there is acquired proximal or distal extremity weakness attributable to cerebrovascular ischemia.			
7. Lateralized abnormal reflexes (to include pathologically brisk deep tendon reflexes, Babinski signs, others)	☐	☐	☐
Indicate as present if it is suspected that there are brisk reflexes or increased tone attributable to cerebrovascular ischemia.			
8. Cortical visual field loss	☐	☐	☐
This involves homonymous hemianopsia or quadrantanopsia, or cortical blindness, excluding visual field loss due to optic nerve disease or injury.			
9. Somatosensory loss	☐	☐	☐
This involves sensory loss due to involvement of the cerebrum or brain stem, excluding sensory loss due to spinal-cord injury or peripheral neuropathy.			

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

OTHER FINDINGS	No	Yes	Not Assessed
1. Patient demonstrates spontaneous, disproportionate or involuntary crying or laughing on examination	☐	☐	☐
On the basis of the response and that to any follow-up questions, supplemented by the examiner's observations of the patient, indicate "yes" or "no."			
2. Is magnetic gait apraxia present?	☐	☐	☐
*Indicate whether gait apraxia characteristic of normal-pressure hydrocephalus or bilateral subcortical ischemia is present by selecting **Yes**. This determination should be made based on the neurological exam and does not require an MRI.*			
3. Higher cortical visual problem suggesting posterior cortical atrophy (e.g., prosopagnosia, simultagnosia, Balint's syndrome) or apraxia of gaze	☐	☐	☐
This includes gradual onset and progression of the following types of features: impaired visuoperceptive abilities or difficulty with visual identification of objects, words or faces; features of Balint's syndrome, e.g., inability to perceive a complex visual field as a while (simultanagnosia), difficulty in fixating the eyes (oculomotor apraxia), and inability to move the hand to a specific object by using vision (optic ataxia).			
4. Findings suggestive of progressive supranuclear palsy (PSP), corticobasal syndrome (CBS), or other related disorders	☐	☐	☐
*If any of the findings below consistent with PSP, CBS, or other related disorders are present, select **Yes**; otherwise, select **No**.* - *Findings consistent with PSP: eye movement changes, dysarthria, axial rigidity, gait disorder, apraxia of speech* - *Findings consistent with CBS: apraxia, cortical sensory deficits, ataxia, alien limb, myoclonus* - *Dystonia consistent with CBS, PSP, or related disorder*			
5. Findings suggesting ALS (e.g., muscle wasting, fasciculations, upper motor neuron and/or lower motor neuron signs)	☐	☐	☐

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

COGNITIVE DIAGNOSIS

Date of Evaluation: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)

SYNDROMIC DIAGNOSIS

☐ Normal Cognition ☐ Impaired, Not MCI

☐ MCI ☐ Dementia

Normal Cognition: *Select if the subject has normal cognition and does not have behavior that is sufficient to diagnose MCI or dementia due to FTD or DLB. Normal cognition is defined as: 1.) No diagnosis of MCI or dementia; and 2.) Either CDR=0 or neuropsychological testing within normal range (or both).*

Dementia: *Review the criteria listed below to determine whether the subject meets the criteria for all-cause dementia. These criteria are modified from the McKhann all-cause dementia criteria (2011) to allow a single domain to be affected.*

The subject has cognitive or behavioral (neuropsychiatric) symptoms that meet all of the following criteria:

- *Interfere with ability to function as before at work or at usual activities?*
- *Represent a decline from previous levels of functioning?*
- *Are not explained by delirium or major psychiatric disorder?*
- *Include cognitive impairment detected and diagnosed through a combination of 1) history-taking and 2) objective cognitive assessment (bedside or neuropsychological testing)?*

AND

Impairment in one or more of the following domains.*

– Impaired ability to acquire and remember new information
– Impaired reasoning and handling of complex tasks, poor judgment
– Impaired visuospatial abilities
– Impaired language functions
– Changes in personality, behavior, or comportment
** In the event of single-domain impairment (e.g., language in PPA, behavior in bvFTD, posterior cortical atrophy), the subject must not fulfill criteria for MCI.*

MCI: *Select if the subject has a cognitive complaint that is not normal for age, has cognitive decline but does not have dementia, and has essentially normal functional activities*

Impaired, Not MCI*: Select if you judge the subject to be cognitively impaired, yet the subject's presentation, test results, symptoms, and clinical evaluation are not consistent with MCI and do not allow you to select Present for MCI*

Age of Onset: ___ ___ ☐ Unknown

	Present	Primary	Contributing	

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

PRIMARY ETIOLOGICAL DIAGNOSES	No	Yes			Non-contributing
1. Alzheimer's disease	☐	☐	☐	☐	☐

The AD dementia criteria listed below are excerpted and condensed from the 2011 NIA-AA criteria for AD dementia (McKhann et al., 2011). The diagnosis of dementia due to Alzheimer's disease: Recommendations from the National Institute on Aging and the Alzheimer's Association workgroups. See the original paper for details.

A. Probable AD dementia is diagnosed when the patient:

1. Meets criteria for dementia, and has the following characteristics:

2. Insidious onset. Symptoms have a gradual onset over months to years; and

3. Clear-cut history of worsening of cognition by report or observation; and

4. The initial and most prominent cognitive deficits are evident on history and examination in one of the following categories.

(1) Amnestic disorder: The most common syndromic presentation of AD dementia.

(2) Non-amnestic disorders:

- *Language disorder*
- *Visuospatial disorder*
- *Executive and behavioral disorder*

5. Exclusions: The diagnosis of probable AD dementia should not be applied when there is evidence of:

(a) substantial concomitant cerebrovascular disease or

(b) core features of dementia with Lewy bodies other than dementia itself; or

(c) prominent features of behavioral variant frontotemporal dementia; or

(d) prominent features of semantic variant primary progressive aphasia or non-fluent/agrammatic variant primary progressive aphasia; or

(e) evidence for another concurrent, active neurological disease, or a non-neurological medical co-morbidity or medication use that could have a substantial impact on cognition.

B. Possible AD dementia is diagnosed when the patient meets one of the two following criteria:

1. Atypical course: Meets the core clinical criteria (1) and (4) (above) for probable AD dementia, but either had a sudden onset of cognitive impairment or demonstrates insufficient historical detail or objective cognitive documentation of progressive decline, or

2. Etiologically mixed presentation: Meets all core clinical criteria (1) through (4) (above) for probable AD dementia but has evidence of:

(a) concomitant cerebrovascular disease or

(b) features of dementia with Lewy bodies other than the dementia itself; or

(c) evidence for another neurological disease or a non-neurological medical co-morbidity or medication use that could have a substantial impact on cognition.

The following table is excerpted from the 2011 NIA-AA criteria for MCI due to AD (Albert et al., 2011):

Summary of clinical and cognitive evaluation for MCI due to AD

Establish clinical and cognitive criteria

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Cognitive concern reflecting a change in cognition reported by patient or informant or clinician (i.e., historical or observed evidence of decline over time)
Objective evidence of impairment in one or more cognitive domains, typically including memory (i.e., formal or bedside testing to establish level of cognitive function in multiple domains)
Largely preserved independence in functional abilities
Not demented
Examine etiology of MCI consistent with AD pathophysiological process
Rule out vascular, traumatic, medical causes of cognitive decline, where possible
Provide evidence of longitudinal decline in cognition, when feasible
Report history consistent with AD genetic factors, where relevant
*If Alzheimer's disease is not present, select **No** for Questions 1, and leave the **Primary, Contributing,** and **Non-contributing** boxes unchecked.*
***For subjects with cognitive impairment:** If Alzheimer's disease is present, select **Present** and indicate whether it is thought to be the **Primary** or **Contributing** cause of the cognitive impairment. Probable AD can be indicated as **Primary** or **Contributing**. On the contrary, Possible Alzheimer's disease (atypical course or seemingly mixed etiologies) should not be marked as **Primary**; the only exception is when there is an atypical course, positive biomarker evidence for AD, and no compelling clinical or biomarker evidence for another primary etiology.*
***For subjects with normal cognition:** If the subject has normal cognition and either sufficient biomarker evidence for Alzheimer's disease or a known genetic mutation, select **No** for **Present** and select the **Non-contributing** box.*

	Present		Primary	Contributing	Non-contributing
	No	Yes			
2. Lewy body disease	☐	☐	☐	☐	☐

Refer to the papers McKeith et al., 2017 (see DLB criteria on pages 99 – 100) and Litvan et al., 2003 (see criteria table below) to assess the presence of Lewy body disease. Additional details concerning the PD criteria are listed under Question 2a.
***For subjects with cognitive impairment:** If Lewy body disease (DLB or Parkinson's disease) is present, select **Present**, and indicate whether it is thought to be the **Primary** or **Contributing** cause of the cognitive impairment. If Lewy body disease is not present, select 'No' for 'Present' and leave all remaining boxes for Questions 2 unchecked.*
***For subjects with normal cognition:** If the subject has normal cognition but has a clinical diagnosis of Parkinson's disease, select **Yes** for **Present** and select the **Non-contributing** box.*

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

	Present		Primary	Contributing	Non-contributing
	No	Yes			
If Present: 2a. Parkinson's disease	☐	☐			

*Select **Yes** for **Present** if the subject has Parkinson's disease.*
Use the following criteria, excerpted from SIC Task Force Appraisal of Clinical Diagnostic Criteria for Parkinsonian Disorders (Litvan et al., 2003):

UK Parkinson's Disease Society Brain Bank Clinical Diagnostic Criteria

Inclusion criteria	Exclusion criteria	Supportive criteria
Bradykinesia (slowness of initiation of voluntary movement with progressive reduction in speed and amplitude of repetitive actions); And at least one of the following: • Muscular rigidity. • 4- to 6-Hz rest tremor. • Postural instability not caused by primary visual, vertibular, cerebellar, or proprioceptive dysfunction.	History of repeated strokes with stepwise progression of parkinsonian features. History of repeated head injury. History of definite encephalitis. Oculogyric crises. Neuroleptic treatment at onset of symptoms. More than one affected relative. Sustained remission. Strictly unilateral features after 3 years. Supranuclear gaze palsy. Cerebellar signs. Early severe autonomic involvement. Early severe dementia with disturbances of memory, language, and praxis. Babinski sign. Presence of cerebral tumor or communicating hydrocephalus on CT scan. Negative response to large doses of levodopa (if malabsorption excluded). MPTP exposure.	(Three or more required for diagnosis of definite PD): • Unilateral onset. • Rest tremor present. • Progressive disorder. • Persistent asymmetry affecting side of onset most. • Excellent response (70%–100%) to levodopa. • Severe levodopa-induced chorea. • Levodopa response for 5 years or more. • Clinical course of 10 years or more.

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

	Present		Primary	Contributing	Non-contributing
	No	Yes			
3. Vascular brain injury (based on clinical or imaging evidence)	☐	☐	☐	☐	☐

*If there is evidence of significant vascular brain injury confirmed by clinical or neuroimaging studies, select **Yes** for **Present** for Question 3. Significant vascular brain injury includes either:*
• CLINICAL EVIDENCE of symptomatic stroke (i.e., abrupt onset of focal neurological signs)
– OR –
• NEUROIMAGING EVIDENCE of one or more of the following:
– cystic infarcts (large or small)
– significant white matter changes (Grade 7–8+ on Cardiovascular Health Study Scale)
– intraparenchymal hemorrhage
– multiple microbleeds
If the subject has no clinical evidence of symptomatic stroke and neuroimaging studies do not indicate evidence of significant vascular brain injury, select 'No' for 'Present'.
***For subjects with cognitive impairment:** Indicate whether vascular brain injury is thought to be the **Primary** cause, a **Contributing** cause, or a **Non-contributing** cause of the cognitive impairment.*
*Select **Primary** if the subject has one or more of the following:*
• a temporal relationship between a symptomatic stroke (confirmed by neuroimaging) and cognitive decline;
• imaging evidence of cystic infarction(s) in a cognitive network
• cystic infarct (anywhere in the brain), and imaging evidence of extensive confluent white matter changes (WMH Grade 7–8+), and impairment in executive function.
*If there is clinical evidence of a symptomatic stroke with temporal relationship to cognitive decline but no available supporting neuroimaging, select **Primary** or **Contributing** based on clinical judgment.*
*If there is significant vascular brain injury but no clear temporal or anatomical relationship with cognitive impairment, select **Contributing** or **Non-contributing** based on clinical judgment.*
*If there is a history of gradually progressive cognitive decline preceding a symptomatic stroke in the absence of extensive confluent white matter changes (thereby suggesting an underlying neurodegenerative etiology), select **Contributing** or **Non-contributing** based on clinical judgment.*
***For subjects with normal cognition:** If the subject has normal cognition but has evidence of significant vascular brain injury, select **Yes** for **Present** for Question 3 and select the **Non-contributing** box.*

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

3a. Peri-Ventricular Fazekas Extent Grade	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ Unknown/ N/A
3b. Deep Fazekas Extent Grade	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ Unknown/ N/A
3c. Deep Fazekas Lesion Count Grade	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ Unknown/ N/A

Peri-Ventricular Fazekas Extent Grade:
Grade 0 – No lesions
Grade 1 – Caps or pencil-thin lining
Grade 2 – Smooth haloing
Grade 3 – Irregular WMH extending into DWM

Deep Fazekas Extent Grade
Grade 0 – No lesions
Grade 1 – Punctate lesions
Grade 2 – Beginning confluent lesions
Grade 3 – Confluent lesions

Deep Fazekas Lesion Count Grade
Grade 0 – No lesions
Grade 1 – 1-4 lesions
Grade 2 – 5-9 lesions
Grade 3 – >9 lesions

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

	Present		Primary	Contributing	Non-contributing
	No	Yes			
4. Traumatic brain injury	☐	☐	☐	☐	☐

The definition of TBI below has been condensed from Menon et al. (2010):
TBI is defined as an alteration in brain function, or other evidence of brain pathology, caused by an external force.
A. Alteration in brain function is defined as 1 of the following clinical signs:

- *Any period of loss of or a decreased LOC*
- *Any loss of memory for events immediately before (retrograde amnesia) or after the injury (PTA)*
- *Neurologic deficits (weakness, loss of balance, change in vision, dyspraxia paresis/plegia [paralysis], sensory loss, aphasia, etc.)*
- *Any alteration in mental state at the time of the injury (confusion, disorientation, slowed thinking, etc.)"*

B. or other evidence of brain pathology: Such evidence may include visual, neuroradiologic, or laboratory confirmation of damage to the brain.
C. caused by an external force may include any of the following events:

- *The head being struck by an object*
- *The head striking an object*
- *The brain undergoing an acceleration/deceleration movement without direct external trauma to the head*
- *A foreign body penetrating the brain*
- *Forces generated from events such as a blast or explosion*
- *Or other force yet to be defined*

For subjects with cognitive impairment: *If the subject has had one or more TBIs as defined above, select* ***Present*** *for Question 4 and indicate whether the TBI is thought to be the* ***Primary*** *cause, a* ***Contributing*** *cause, or a* ***Non-contributing*** *cause of the cognitive impairment.*
For subjects with normal cognition: *If the subject has normal cognition but has had one or more TBIs as defined above, select* ***Yes*** *for* ***Present*** *for Question 4 and select the* ***Non-contributing*** *box.*
If the subject has had no previous TBI, select ***No*** *for* ***Present*** *and leave all remaining boxes in Question 4 blank and unchecked.*

If Present: 4a. If present, does the subject have symptoms consistent with chronic traumatic encephalopathy?	☐ No ☐ Yes ☐ Unknown

Refer to the published papers by McKee et al. (2009) and Stern et al. (2013) for additional details on clinical CTE symptoms.
Select ***Yes*** *if the subject has symptoms consistent with chronic traumatic encephalopathy. If the subject does not have symptoms consistent with CTE, select* ***No****. If it is unknown whether the subject has symptoms consistent with CTE, select* ***Unknown****.*

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

	Present		Primary	Contributing	Non-contributing
	No	Yes			
5. Depression	☐	☐	☐	☐	☐
If Present: 5a. ☐ Untreated ☐ Treated with medication and/or counseling					

*Consult the Diagnostic and Statistical Manual of Mental Disorders regarding the diagnosis of depression. If depression is not present, select 'No' for 'Present' and leave all remaining boxes for Questions 5 and 5a blank/unchecked. If active depression (regardless of whether it is active but successfully treated with medication or counseling) is present, select **Yes** for **Present**, and indicate whether it is thought to be the **Primary** cause, a **Contributing** cause, or a **Non-contributing** cause of the cognitive impairment. If the subject has normal cognition but has active depression, select **Yes** for **Present** for Question 5 and select the **Non-contributing** box.*

	Present		Primary	Contributing	Non-contributing
	No	Yes			
6. Cognitive impairment due to alcohol abuse	☐	☐	☐	☐	☐
If Present: 6a. Current alcohol abuse	☐ No	☐ Yes	☐ Unknown		

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

RELATED ETIOLOGICAL DIAGNOSES	Present	Primary	Contributing	Non-contributing
7. Multiple system atrophy	☐	☐	☐	☐
Refer to the diagnostic criteria in Gilman et al. (2008) when assessing the presence of multiple system atrophy (MSA). *If MSA is present, select **Present** for Question 7, and indicate whether it is **Primary**, **Contributing**, or **Non-contributing** to the observed cognitive impairment, if applicable. If the subject has normal cognition but clinical symptoms sufficient for a diagnosis of MSA, select **Present** for Question 7 and select the **Non-contributing** checkbox.* *If MSA is not present, leave all checkboxes for Questions 7 blank/unchecked.*				
8. Frontotemporal lobar degeneration	☐	☐	☐	☐
Refer to the diagnostic criteria listed below when assessing the presence of Frontotemporal lobar degeneration (FTLD). The following diseases fall under the category of FTLD: progressive supranuclear palsy (PSP), corticobasal degeneration (CBD), FTLD with motor neuron disease, or FTLD not otherwise specified (NOS). *If any of the diseases listed above are present, select **Present** and indicate whether it is thought to be the **Primary** cause, a **Contributing** cause, or a **Non-contributing** cause of the cognitive impairment. If any disease is present but the subject has normal cognition, select **Present** for Question 8 and select the **Non-contributing** box.* *If the subject does not have any of the listed diseases, leave all boxes for Question 8 unchecked.* *PSP: Use the criteria by Bensimon et al. (2009) to diagnose PSP* *CBD: Refer to diagnostic criteria by Armstrong et al. (2013) when assessing the presence of CBD.* *FTLD with motor neuron disease: Use the following criteria, adapted from El Escorial revisited: Revised criteria for the diagnosis of amyotrophic lateral sclerosis (Brooks et al., 2000)* *FTLD NOS: Select **Present** for Question 8 if FTLD not otherwise specified (NOS) is present*				

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

	Present	Primary	Contributing	Non-contributing
9. Essential tremor	☐	☐	☐	☐
Refer to the consensus criteria (Deuschl et al., 1998) for essential tremor. If essential tremor is not present, leave all checkboxes in Question 9 blank/unchecked. ***For subjects with cognitive impairment:*** *If essential tremor is present, select* ***Present*** *and indicate whether it is thought to be the* ***Primary*** *cause, a* ***Contributing*** *cause, or a* ***Non-contributing*** *cause of the cognitive impairment.* ***For subjects with normal cognition:*** *If the subject has normal cognition but has essential tremor features, select* ***Present*** *and select the* ***Non-contributing*** *box.*				
10. Down syndrome	☐	☐	☐	☐
If Down syndrome is present, select ***Present*** *and indicate whether it is thought to be the* ***Primary*** *cause, a* ***Contributing*** *cause, or a* ***Non-contributing*** *cause of the cognitive impairment, if applicable.* *If Down syndrome is not present, leave all boxes for Question10 blank/unchecked. If the subject has normal cognition but has Down syndrome, select* ***Present*** *for Question 10 and select the* ***Non-contributing*** *checkbox.*				
11. Huntington's disease	☐	☐	☐	☐
If Huntington's disease is present, select ***Present*** *for Question 11, and indicate whether it is thought to be the* ***Primary*** *cause, a* ***Contributing*** *cause, or a* ***Non-contributing*** *cause of the cognitive impairment, if applicable. If Huntington's disease is not present, leave all boxes for Question11 blank/unchecked. If the subject has normal cognition but has Huntington's disease features or a known mutation, select* ***Present*** *and select the* ***Non-contributing*** *checkbox.*				
12. Prion disease (CJD, other)	☐	☐	☐	☐
Refer to the paper by Puoti et al. (2012) regarding the clinical diagnosis of prion disease. *If prion disease is not present, leave all checkboxes in Question11 blank/unchecked.* *Select* ***Present*** *if prion disease (Creutzfeldt-Jakob disease or other type) is present, and indicate whether it is thought to be the* ***Primary*** *cause, a* ***Contributing*** *cause, or a* ***Non-contributing*** *cause of the cognitive impairment. If the subject has normal cognition but has tested positive for prion disease, select* ***Present*** *for Question 12 and select the* ***Non-contributing*** *checkbox.*				
13. Hydrocephalus	☐	☐	☐	☐
If hydrocephalus is not present, leave all boxes in Question13 blank/unchecked. If hydrocephalus is present, select ***Present****, and indicate whether it is thought to be the* ***Primary*** *cause, a* ***Contributing*** *cause, or a* ***Non-contributing*** *cause of the cognitive impairment. If the subject has normal cognition, but has other non-cognitive features of hydrocephalus, select* ***Present*** *for Question 13 and select the* ***Non-contributing*** *checkbox.*				

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

	Present	Primary	Contributing	Non-contributing
14. Epilepsy	☐	☐	☐	☐
*Refer to the paper by Fisher et al. (2014) for clinical symptoms consistent with epilepsy. If epilepsy is not present, leave all boxes in Question14 blank/unchecked. If epilepsy is present, select **Present**, and indicate whether it is thought to be the **Primary** cause, a **Contributing** cause, or a **Noncontributing** cause of the cognitive impairment. If the subject has normal cognition but has other non-cognitive features of epilepsy, select **Present** for Question 14 and select the **Non-contributing** checkbox.*				
15. CNS neoplasm	☐	☐	☐	☐
If present: 15a. ☐ Benign ☐ Malignant				
*If CNS neoplasm (benign or malignant) is not present, leave all boxes for Questions 15 and 15a blank/ unchecked. If CNS neoplasm is present, select **Present**, and indicate whether it is thought to be the **Primary** cause, a **Contributing** cause, or a **Non-contributing** cause of the cognitive impairment. If the subject has normal cognition and has CNS neoplasm, select **Present** for Question 15 and select the **Non-contributing** checkbox.*				
16. Human immunodeficiency virus (HIV)	☐	☐	☐	☐
Recent publications outline updated research criteria for determining the presence of an HIV-associated neurocognitive disorder — for instance, the paper by Antinori et al. (2007). ***For subjects with cognitive impairment:** If HIV is present, select, and indicate whether it is thought to be the **Primary** cause, a **Contributing** cause, or a **Non-contributing** cause of the cognitive impairment.* ***For subjects with normal cognition:** If the subject has normal cognition and has HIV, select **Present** for Question 16 and select the **Non-contributing** checkbox.* *If HIV is not present, leave all boxes for Question16 blank/unchecked.*				

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Questions 17 – 21: *Consult the Diagnostic and Statistical Manual of Mental Disorders regarding the diagnosis of the psychiatric conditions listed in Questions 17 – 21. If the psychiatric disorder is not present, leave all questions related to the particular psychiatric disorder blank/unchecked. If the psychiatric condition (regardless of whether it is active but successfully treated with medication or counseling) is present, select* ***Present,*** *and indicate whether it is thought to be the* ***Primary*** *cause, a* ***Contributing*** *cause, or a* ***3=Non-contributing*** *cause of the cognitive impairment. If the subject has normal cognition but has the psychiatric disorder, select* ***Present*** *and select the* ***Non-contributing*** *checkbox.*

	Present	Primary	Contributing	Non-contributing
17. Bipolar disorder	☐	☐	☐	☐
18. Schizophrenia or other psychosis	☐	☐	☐	☐
19. Anxiety disorder	☐	☐	☐	☐
20. Delirium	☐	☐	☐	☐
21. Post-traumatic stress disorder (PTSD)	☐	☐	☐	☐
22. Other psychiatric disease (specify): _____ _____	☐	☐	☐	☐

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

	Present	Primary	Contributing	Non-contributing
23. Cognitive impairment due to:				
23a. Other neurologic, genetic, or infectious conditions not listed above (specify): _____ _____ _____	☐	☐	☐	☐
*If the subject has cognitive impairment due to a neurological, genetic, or infectious condition other than those described in previous questions, select **Present**, specify the etiologic cause in the **Specify** field, and indicate whether the etiology is the **Primary** cause, a **Contributing** cause, or a **Non-contributing** cause of the observed cognitive impairment.*				
23b. Other substance abuse	☐	☐	☐	☐
23c. Systemic disease/medical illness	☐	☐	☐	☐
23d. Medications	☐	☐	☐	☐
23e. Cognitive impairment NOS: _____ _____	☐	☐	☐	☐

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

MoCA (MONTREAL COGNITIVE ASSESSMENT)

Please refer to the MarkVCID Evaluator's Instructions Manual for details instructions on the administration of this assessment

Was any part of the MoCA administered?

☐ No ☐ Yes

If No, please provide the primary reason: ☐ Physical problem ☐ Verbal refusal

☐ Cognitive/behavior problem ☐ Other problem (specify): _____

_____

Date of Examination: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)

Language of test administration:

☐ English

☐ Spanish

☐ Other (specify): _____

KEY: If the subject cannot complete any of the following exams, please give the reason by entering one of the following codes:

95 = Physical problem
96 = Cognitive/behavior problem
97 = Other problem
98 = Verbal refusal

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Score is 'Not Assessed' if any of the MoCA items that contribute to the score are missing (i.e., items 1–6, 8-14, and 17-22). Items 7, 15, and 16 are not part of the MoCA score calculation; therefore, these items can have missing values (95, 96, 97, or 98). The MoCA Score will still be computed as long as items 1–6, 8-14, and 17-22 are all non-missing.	
Scores for items 1-5 correspond to the Visuospatial / executive section on the MoCA worksheet	
1. Visuospatial/ executive — Trails:	___ ___ [0-1, 95-98]
2. Visuospatial/ executive — Cube:	___ ___ [0-1, 95-98]
3. Visuospatial/ executive — Clock contour:	___ ___ [0-1, 95-98]
4. Visuospatial/ executive — Clock numbers:	___ ___ [0-1, 95-98]
5. Visuospatial/ executive — Clock hands:	___ ___ [0-1, 95-98]
Score for item 6 corresponds to the Naming section on the MoCA worksheet	
6. Language — Naming:	___ ___ [0-3, 95-98]
Score for item 7 corresponds to the Memory section on the MoCA worksheet	
7. Memory — Registration (two trials):	___ ___ [0-10, 95-98]
Scores for items 8-10 correspond to the Attention section on the MoCA worksheet	
8. Attention — Digits:	___ ___ [0-2, 95-98]
9. Attention — Letter A:	___ ___ [0-1, 95-98]
10. Attention — Serial 7s:	___ ___ [0-3, 95-98]
Scores for items 11-12 correspond to the Language section on the MoCA worksheet	
11. Language — Repetition:	___ ___ [0-2, 95-98]
12. Language — Fluency:	___ ___ [0-1, 95-98]
Score for item 13 corresponds to the Abstraction section on the MoCA worksheet	

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

13. Abstraction:	__ __ [0-2, 95-98]
Scores for items 14-16 correspond to the Delayed Recall section on the MoCA worksheet	
14. Delayed recall — No cue: *(if not completed, enter reason code and skip to question 17)*	__ __ [0-5, 95-98]
15. Delayed recall — Category cue:	__ __ [0-5, 95-98]
16. Delayed recall — Recognition:	__ __ [0-5, 95-98]
Scores for items 17-22 correspond to the Orientation section on the MoCA worksheet	
17. Orientation — Date:	__ __ [0-1, 95-98]
18. Orientation — Month:	__ __ [0-1, 95-98]
19. Orientation — Year:	__ __ [0-1, 95-98]
20. Orientation — Day:	__ __ [0-1, 95-98]
21. Orientation — Place:	__ __ [0-1, 95-98]
22. Orientation — City:	__ __ [0-1, 95-98]

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ___ ___/ ___ ___/ ___ __ ___ ___	**Evaluator Initials:** ____ ____ ____
Study Visit:	

NEUROPSYCHOLOGICAL TESTING BATTERY

Please refer to the MarkVCID Evaluator's Instructions Manual for details instructions on the administration of this assessment

Was any part of the remainder of the Neuropsychological Testing Battery administered?

☐ No ☐ Yes

If No, please provide the primary reason: ☐ Physical problem ☐ Verbal refusal

☐ Cognitive/behavior problem ☐ Other problem (specify): _____

_____

Date of Examination: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)

Indicate the primary language used when administering the remainder of the tests.

Language of test administration:

☐ English

☐ Spanish

☐ Other (specify): _____

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

KEY: If the subject cannot complete any of the following exams, please give the reason by entering one of the following codes:

95 = Physical problem
96 = Cognitive/behavior problem
97 = Other problem
98 = Verbal refusal

Scores for item 1 correspond to the Craft Store 21 Recall (Immediate) Worksheets

1. Craft Story 21 Recall (Immediate):
   a) If test not completed, enter reason code and skip to question 2a: ___ ___ [95-98]
   b) Total story units recalled, verbatim scoring: ___ ___ [0-44]
   c) Total story units recalled, paraphrase scoring: ___ ___ [0-25]

Scores for item 2 correspond to the Craft Store 21 Recall (Delayed) Worksheets

2. Craft Story 21 Recall (Delayed):
   a) If test not completed, enter reason code and skip to question 3a: ___ ___ [95-98]
   b) Total story units recalled, verbatim scoring: ___ ___ [0-44]
   c) Total story units recalled, paraphrase scoring: ___ ___ [0-25]
   d) Delay time (minutes): ☐ Unknown ___ ___ [0-85]
   e) Cue ("boy") needed: ☐ No ☐ Yes

Scores for items 3-4 correspond to the Number Span Test (Forward & Backward) Worksheets

3. Number Span Test — Forward:
   a) If test not completed, enter reason code and skip to question 4a: ___ ___ [95-98]
   b) Number of correct trials: ___ ___ [0-14]
   c) Longest span forward: ___ ___ [0, 3-9]

4. Number Span Test — Backward:
   a) If test not completed, enter reason code and skip to question 5a: ___ ___ [95-98]
   b) Number of correct trials: ___ ___ [0-14]
   c) Longest span backward: ___ ___ [0, 2-8]

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Scores for item 5 correspond to the Category Fluency Worksheets

5. Category Fluency – Animals:
   a) If test not completed, enter reason code and skip to question 6a: ___ ___ [95-98]
   b) Total number of animals named in 60 seconds: ___ ___ [0-77]

Scores for item 6 correspond to the Verbal Fluency Worksheets, administered as part of the MoCA

6. Verbal Fluency – Phonemic Tests (words beginning with F):
   a) If test not completed, enter reason code and skip to question 7a: ___ ___ [95-98]
   b) Number of correct F-words generated in 1 minute: ___ ___ [0-40]
   c) Number of F-words repeated in 1 minute: ___ ___ [0-15]
   d) Number of non-F-words and rule violation errors in 1 minute: ___ ___ [0-15]

Scores for items 7-8 correspond to the Trail Making A & B Worksheets

7. Trail Making Test A:
   a) If test not completed, enter reason code and skip to question 8a: ___ ___ [95-98]
   b) Total number of seconds to complete (if not finished by 150 seconds, enter 150)
      ___ ___ ___ [0-150]
      i. Number of commission errors: ___ ___ [0-40]
      ii. Number of correct lines: ___ ___ [0-24]

8. Trail Making Test B:
   a) If test not completed, enter reason code and skip to question 9a: ___ ___ [95-98]
   b) Total number of seconds to complete (if not finished by 300 seconds, enter 300):
      ___ ___ ___ [0-300]
      i. Number of commission errors: ___ ___ [0-40]
      ii. Number of correct lines: ___ ___ [0-24]

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Scores for item 9 correspond to the Multilingual Naming Test (MINT) Worksheets
*If no semantic cues were given, select **N/A** for Question 9e.*
*If no phonemic cues were given, select **N/A** for Question 9g.*

9. Multilingual Naming Test (MINT):
   a) If test not completed, enter reason code and skip to question 10a: ___ ___ [95-98]
   b) Total score (9c + 9e): ___ ___ [0-32]
   c) Total correct without any cues (Uncued): ___ ___ [0-32]
   d) Semantic cues – Number given: ___ ___ [0-32]
   e) Semantic cues – Number correct with cue: ☐ N/A ___ ___ [0-32]
   f) Phonemic cues – Number given: ___ ___ [0-32]
   g) Phonemic cues – Number correct with cue: ☐ N/A ___ ___ [0-32]

Scores for item 10 correspond to your sites specific scoring instructions for the CVLT, CVLT-SF, HVLT, SEVLT, or other with list learning with immediate/delay/recognition

10. Word list learning with immediate/delay/recognition:
   a) Name of test: ☐ HVLT ☐ CVLT
      ☐ CVLT-SF ☐ SEVLT [Spanish]
      ☐ Other (specify): _____
   b) Total number of words on list: ___ ___
   c) If test not completed, please select reason code: ___ ___ [95-98]
   d) Learning Trial 1: ___ ___
   e) Learning Trial 2: ___ ___
   f) Learning Trial 3: ___ ___
   g) Learning Trial 4: ☐ N/A ___ ___
   h) Learning Trial 5: ☐ N/A ___ ___
   i) Delay duration (if multiple options choose longest): ___ ___
   j) Delayed recall (if multiple delay options, choose longest): ___ ___
   k) Recognition hits: ___ ___
   l) Recognition false positives: ___ ___

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

CDR (CLINICAL DEMENTIA RATING)

Please refer to the MarkVCID Evaluator's Instructions Manual for details instructions on the administration of this assessment

Was the CDR administered?

☐ No ☐ Yes

If No, please provide the primary reason: ☐ Physical problem ☐ Verbal refusal

☐ Cognitive/behavior problem ☐ Other problem (specify): _____

_____

Date of Evaluation: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)

Section 1: Standard CDR

Please enter score below:	IMPAIRMENT				
	None – 0	Questionable – 0.5	Mild – 1	Moderate – 2	Severe – 3
1. Memory ___ . ___	No memory loss, or slight inconsistent forgetfulness	Consistent slight forgetfulness; partial recollection of events; "benign" forgetfulness	Moderate memory loss, more marked for recent events; defect interferes with everyday activities	Severe memory loss; only highly learned material retained; new material rapidly lost	Severe memory loss; only fragments remain
2. Orientation ___ . ___	Fully oriented	Fully oriented except for slight difficulty with time relationships	Moderate difficulty with time relationships; oriented for place at examination; may have geographic disorientation elsewhere	Severe difficulty with time relationships; usually disoriented to time, often to place	Oriented to person only
3. Judgment and problem solving ___ . ___	Solves everyday problems, handles business and financial affairs well; judgment good in relation to past performance	Slight impairment in solving problems, similarities, and differences	Moderate difficulty in handling problems, similarities, and differences; social judgment usually maintained	Severely impaired in handling problems, similarities, and differences; social judgment usually impaired	Unable to make judgments or solve problems

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Please enter score below:	IMPAIRMENT				
	None – 0	Questionable – 0.5	Mild – 1	Moderate – 2	Severe – 3
4. Community affairs ___ . ___	Independent function at usual level in job, shopping, volunteer and social groups	Slight impairment in these activities	Unable to function independently at these activities, although may still be engaged in some; appears normal to casual inspection	No pretense of independent function outside the home; appears well enough to be taken to functions outside the family home	No pretense of independent function outside the home; appears too ill to be taken to functions outside the family home
5. Home and hobbies ___ . ___	Life at home, hobbies, and intellectual interests well maintained	Life at home, hobbies, and intellectual interests slightly impaired	Mild but definite impairment of function at home; more difficult chores abandoned; more complicated hobbies and interests abandoned	Only simple chores preserved; very restricted interests, poorly maintained	No significant function in the home
6. Personal care ___ . 0	Fully capable of self-care (= 0).		Needs prompting	Requires assistance in dressing, hygiene, keeping of personal effects	Requires much help with personal care; frequent incontinence
8. ___ ___ STANDARD GLOBAL CDR					

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Section 2: Supplemental CDR					
Please enter score below:	IMPAIRMENT				
	None – 0	Questionable – 0.5	Mild – 1	Moderate – 2	Severe – 3
9. Behavior, comportment, and personality __ . __	Socially appropriate behavior	Questionable changes in comportment, empathy, appropriateness of actions	Mild but definite changes in behavior	Moderate behavioral changes, affecting interpersonal relationships and interactions in a significant manner	Severe behavioral changes, making interpersonal interactions all unidirectional
10. Language __ . __	No language difficulty, or occasional mild tip-of-the tongue	Consistent mild word-finding difficulties; simplification of word choice; circumlocution; decreased phrase length; and/or mild comprehension difficulties	Moderate word-finding difficulty in speech; cannot name objects in environment; reduced phrase length and/or agrammatical speech and/or reduced comprehension in conversation and reading	Moderate to severe impairments in either speech or comprehension; has difficulty communicating thoughts; writing may be slightly more effective	Severe comprehension deficits; no intelligible speech

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

GDS (GERIATRIC DEPRESSION SCALE)

Please refer to the MarkVCID Evaluator's Instructions Manual for details instructions on the administration of this assessment

Was the GDS administered?

☐ No ☐ Yes

If No, please provide the primary reason: ☐ Physical problem ☐ Verbal refusal

☐ Cognitive/behavior problem ☐ Other problem (specify): _____

_____

Date of Evaluation: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)

Scores for items 1-15 correspond to the Geriatric Depression Scale (GDS) Worksheet

	Yes	No	Did not answer
1. Are you basically satisfied with your life?	☐	☐	☐
2. Have you dropped many of your activities and interests?	☐	☐	☐
3. Do you feel that your life is empty?	☐	☐	☐
4. Do you often get bored?	☐	☐	☐
5. Are you in good spirits most of the time?	☐	☐	☐
6. Are you afraid that something bad is going to happen to you?	☐	☐	☐

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ___ ___/ ___ ___/ ___ __ ___ ___	**Evaluator Initials:** ____ ____ ____
Study Visit:	

	Yes	No	Did not answer
7. Do you feel happy most of the time?	☐	☐	☐
8. Do you often feel helpless?	☐	☐	☐
9. Do you prefer to stay at home, rather than going out and doing new things?	☐	☐	☐
10. Do you feel you have more problems with memory than most people?	☐	☐	☐
11. Do you think it is wonderful to be alive?	☐	☐	☐
12. Do you feel pretty worthless the way you are now?	☐	☐	☐
13. Do you feel full of energy?	☐	☐	☐
14. Do you feel that your situation is hopeless?	☐	☐	☐
15. Do you think that most people are better off than you are?	☐	☐	☐

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

LABORATORY TESTS

Date of Collection: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)

Only enter lab test results from labs conducted within the last 3 months. Individual dates labs were conducted will not be captured. Please enter the date the lab data was collected or retrieved from medical records for 'Date of Collection.'

If fasting conditions are unknown, mark "not fasting".

*All tests denoted with * are required. Cholesterol related labs, blood sugar, and homocysteine should be collected under fasting conditions when possible.*

PHYSIOLOGIC MEASURES

Measure	Fasting	Result
1. HS-CRP	N/A	___ mg/L ☐ Not Done
2. HbA1c*	N/A	___ mmol/mol ☐ Not Done
3. Blood Sugar	☐ Fasting >8 hours ☐ Not fasting	___ mmol/L ☐ Not Done
4. Serum cholesterol*	☐ Fasting >8 hours ☐ Not fasting	___ mg/dL ☐ Not Done
5. HDL cholesterol*	☐ Fasting >8 hours ☐ Not fasting	___ mg/dL ☐ Not Done
6. LDL cholesterol*	☐ Fasting >8 hours ☐ Not fasting	___ mg/dL ☐ Not Done
7. Triglycerides*	☐ Fasting >8 hours ☐ Not fasting	___ mg/dL ☐ Not Done
8. Homocysteine	☐ Fasting >8 hours ☐ Not fasting	___ mg/dL ☐ Not Done

GENETICS

Have any genetic tests been performed? ☐ No ☐ Yes

If yes:

APOE genotype: ☐ E2/E2 ☐ E2/E3 ☐ E2/E4 ☐ E3/E3 ☐ E3/E4 ☐ E4/E4 ☐ Not Done

Has a GWAS been completed? ☐ No ☐ Yes

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

SAMPLE COLLECTION: CSF COLLECTION
Status: ☐ Collected ☐ Not Collected
If not collected, reason not collected: _____ _____
Date CSF Samples Collected: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)
Time since last meal: ___ ___ hours
Time Collected: ___ ___ : ___ ___ (24 hour clock)
Collector's Initials: ___ ___ ___ (enter dash if no middle name)
Pre-Centrifugation sample: Appearance: ☐ Clear ☐ Cloudy Color: ☐ Pink ☐ Other (specify): _____ _____
Number of 0.25 mL aliquots: ___ ___

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Were there any deviations? ☐ No ☐ Yes

If YES, indicate deviations below (select all that apply):

☐ Sample not placed on dry ice or in -80º C freezer immediately after aliquoting

If selected, please select one of the following:

☐ Placed on dry ice or in freezer within 30 minutes of aliquoting
☐ Placed on dry ice or in freezer 30-60 minutes after aliquoting
☐ Placed on dry ice or in freezer 60+ minutes after aliquoting

☐ The participant was NOT fasting for a minimum of 6 hours prior to collection

☐ Other deviation (specify): _____

_____

_____

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

SAMPLE COLLECTION: PLASMA COLLECTION
Status: ☐ Collected ☐ Not Collected
If not collected, reason not collected: _____ _____
Date Plasma Samples Collected: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)
Time since last meal: ___ ___ (hours)
Time Collected: ___ ___ : ___ ___ (24 hour clock)
Collector's Initials: ___ ___ ___ (enter dash if no middle name)
Number of 0.25 mL plasma aliquots: ___ ___
Number of 1 mL packed cell aliquots for DNA: ___ ___
Temperature of Centrifugation: ___ ___ °C
Did plasma remain pink after centrifugation, indicating hemolysis? ☐ No ☐ Yes
Storage temperature: ___ ___ °C

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Were there any deviations? ☐ No ☐ Yes

If YES, indicate deviations below (select all that apply):

☐ Sample tube was not inverted 5-10 times

☐ Sample not spun within 2 hours of collection
If selected, please select one of the following:
- ☐ Spun 2-3 hours after collection
- ☐ Spun 3-4 hours after collection
- ☐ Spun 4+ hours after collection

☐ Sample not spun at 2000g
If selected, please select one of the following:
- ☐ Spun slower than 2000g
- ☐ Spun faster than 2000g

☐ Sample not spun for 10 minutes
If selected, please select one of the following:
- ☐ Spun <10 minutes
- ☐ Spun >10 minutes

☐ Sample not placed on dry ice or in -80º C freezer immediately after aliquoting
If selected, please select one of the following:
- ☐ Placed on dry ice or in freezer within 30 minutes of aliquoting
- ☐ Placed on dry ice or in freezer 30-60 minutes after aliquoting
- ☐ Placed on dry ice or in freezer 60+ minutes after aliquoting

☐ Other deviation (specify): _____

_____

_____

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

SAMPLE COLLECTION: SERUM COLLECTION
Status: ☐ Collected ☐ Not Collected
If not collected, reason not collected: _____ _____
Date Serum Samples Collected: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)
Time since last meal: ___ ___ (hours)
Time Collected: ___ ___ : ___ ___ (24 hour clock)
Collector's Initials: ___ ___ ___ (enter dash if no middle name)
Number of 0.25 mL aliquots: ___ ___
Temperature of Centrifugation: ___ ___ °C
Did serum remain pink after centrifugation, indicating hemolysis? ☐ No ☐ Yes
Storage temperature: ___ ___ °C

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Were there any deviations? ☐ No ☐ Yes

If YES, indicate deviations below (select all that apply):

☐ After collection, sample not allowed to sit in vertical position for 30-60 minutes (select all that apply):
- ☐ Sample not kept vertical
- ☐ Sample did not sit for 30-60 minutes after collection
  - If selected, please select one of the following:
    - ☐ Sample sat <30 minutes
    - ☐ Sample sat >60 minutes

☐ Sample not spun at 2000g
- If selected, please select one of the following:
- ☐ Spun slower than 2000g
- ☐ Spun faster than 2000g

☐ Sample not spun for 10 minutes
- If selected, please select one of the following:
- ☐ Spun <10 minutes
- ☐ Spun >10 minutes

☐ Sample not placed on dry ice or in -80º C freezer immediately after aliquoting
- If selected, please select one of the following:
- ☐ Placed on dry ice or in freezer within 30 minutes of aliquoting
- ☐ Placed on dry ice or in freezer 30-60 minutes after aliquoting
- ☐ Placed on dry ice or in freezer 60+ minutes after aliquoting

☐ Other deviation (specify): _____

_____

_____

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

SAMPLE COLLECTION: PLATELET POOR PLASMA (PPP) COLLECTION
Status: ☐ Collected ☐ Not Collected
If not collected, reason not collected: _____ _____
Date PPP Samples Collected: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)
Time Collected: ___ ___ : ___ ___ (24 hour clock)
Collector's Initials: ___ ___ ___ (enter dash if no middle name)
Time since last meal: ___ ___ hours
Number of 0.25 mL aliquots: ___ ___
Did plasma remain pink after centrifugation, indicating hemolysis? ☐ No ☐ Yes
Storage temperature: ___ ___ °C

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Were there any deviations? ☐ No ☐ Yes

If YES, indicate deviations below (select all that apply):

☐ Sample tube was not inverted 5-10 times

☐ Sample not spun within 2 hours of collection
If selected, please complete the following:
Spun ___ ___ hours after collection (round to nearest hour)

☐ Sample not spun at 500g (first centrifugation step)
If selected, please complete the following:
Speed sample spun at: ___ ___ g

☐ Sample not spun for 20 minutes (first centrifugation step)
If selected, please complete the following:
Duration of spin: ___ ___ min

☐ Sample not spun at 20C (first centrifugation step)
If selected, please complete the following:
Temperature of spin: ___ ___ C

☐ Sample not mixed at a 1:1 ratio after first centrifugation step
If selected, please complete the following:
Volume of supernatant (platelet rich plasma): ___ ___ mL
Volume of DBS with additives: ___ ___ mL

☐ Sample not spun at 2,200g (second centrifugation step)
If selected, please complete the following:
Speed sample spun at: ___ ___ g

☐ Sample not spun for 20 minutes (second centrifugation step)
If selected, please complete the following:
Duration of spin: ___ ___ min

Deviations (continued):

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

☐ Sample not spun at 20C (second centrifugation step)
If selected, please complete the following:
Temperature of spin: ___ ___ C

☐ Sample not placed on dry ice or in -80º C freezer immediately after aliquoting
If selected, please select one of the following:
☐ Placed on dry ice or in freezer within 30 minutes of aliquoting
☐ Placed on dry ice or in freezer 30-60 minutes after aliquoting
☐ Placed on dry ice or in freezer 60+ minutes after aliquoting

☐ Other deviation (specify): _____

_____

_____

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

IMAGING	
Was an MRI performed at this visit?	☐ No ☐ Yes
If No, please provide reason:	☐ Claustrophobia ☐ Other reason: _____ _____
Date of Imaging: ___ ___ / ___ ___ / ___ ___ ___ ___ (MM/DD/YYYY)	

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ___ ___/ ___ ___/ ___ __ ___ ___	**Evaluator Initials:** ____ ____ ____
Study Visit:	

OCTA SCREENING WORKSHEET			
Date of OCTA Screening: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)			
Exclusion Criteria *If the subject answers "yes" to any questions under #1-4, please **DO NOT** perform OCTA testing on the subject.*			
Criterion	**No**	**Yes**	**N/A**
1. Have you ever been diagnosed with any of the following eye diseases?			
1.1. Glaucoma	☐	☐	
1.2. Diabetic Retinopathy	☐	☐	
1.3. Advanced Dry Age-Related Macular Degeneration	☐	☐	
1.4. Advanced Wet Age-Related Macular Degeneration	☐	☐	
2. Have you ever had any of the following procedures done?			
2.1. Laser Surgery on either eye for any reason *(excluding cosmetic or refractive procedures such as LASIK or cataract surgery)*	☐	☐	
2.2. Injections into or around either eye *(excluding cosmetic procedures)*	☐	☐	

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Criterion	**No**	**Yes**	**N/A**
3. If you have had your eyes dilated for an examination in the past,			
3.1. Did you have a problem or allergy (excluding blurry vision)? (*Mark not applicable if patient has never had their eyes dilated for an eye examination)*	☐	☐	☐
3.2. Were you told not to get dilated again? (*Mark not applicable if patient has never had their eyes dilated for an eye examination)*	☐	☐	☐
4. Do you take any prescription eye drops (excluding artificial tears)?	☐	☐	
OCTA Enrollment			
If the subject answered "Yes" to any of the exclusion criteria above, please indicate that the subject cannot undergo OCTA testing. *If the subject answered "No" or "N/A" to all of the exclusion criteria above, please indicate that they are enrolled in OCTA testing.* *Please note that the screening criteria above are not entered into the EDC. The response to the question below is recorded on the "OCTA: Initial/Follow-Up" form in the EDC.*			
☐ Subject cannot undergo OCTA testing because of exclusion criteria ☐ Subject is enrolled in OCTA testing and agrees to dilation of right eye. If the subject does not agree to dilation, they are not eligible for enrollment in the study			

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

OCTA: INITIAL

Date of OCTA Scans: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)

Right Eye Dilation

One drop of each of the following should be used in the right eye: Proparacaine 0.5%, Tropicamide 1%, Phenylephrine 2.5%. The drops will burn for a few seconds. Dilation takes 10 minutes. Inform patient that their vision may be temporarily blurred for several hours. If any pain within 24 hours call for evaluation immediately.

☐ Subject's right eye is topically anesthetized with 1-2 drops Proparacaine 0.5%

☐ Subject's right eye is dilated with 1-2 drops each of:

- ☐ Tropicamide 1%
- ☐ Phenylephrine 2.5%
- ☐ Other (specify): _____

(Note: If subject does not appear well dilated after 10 minutes it is reasonable to administer another drop of each dilating drop)

OCTA Scans

Scans of the right eye should be completed first, then the left eye. For each eye, perform the "Angiography 3x3 mm" scans first, followed by the "Optic Disc Cube 200x200" scans. Only scans of signal strength 8 or higher should be saved. Four repeated scans of each region for each eye should be captured.

Scan Number	Signal Strength
Right Eye Angiography 3x3 mm Scan 1	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Angiography 3x3 mm Scan 2	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Angiography 3x3 mm Scan 3	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Angiography 3x3 mm Scan 4	☐ 8 ☐ 9 ☐ 10 ☐ Not Done

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Scan Number	Signal Strength
Right Eye Optic Disc Cube 200x200 Scan 1	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Optic Disc Cube 200x200 Scan 2	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Optic Disc Cube 200x200 Scan 3	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Optic Disc Cube 200x200 Scan 4	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Angiography 3x3 mm Scan 1	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Angiography 3x3 mm Scan 2	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Angiography 3x3 mm Scan 3	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Angiography 3x3 mm Scan 4	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Optic Disc Cube 200x200 Scan 1	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Optic Disc Cube 200x200 Scan 2	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Optic Disc Cube 200x200 Scan 3	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Optic Disc Cube 200x200 Scan 4	☐ 8 ☐ 9 ☐ 10 ☐ Not Done

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ __ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Please answer the questions below	
1. Has the subject seen an eye doctor in the past 5 years?	☐ No ☐ Yes ☐ Unknown
1a. *If yes,* has the subject released the medical records from this time period?	☐ No ☐ Yes ☐ Unknown
2. Does the subject wear glasses or contacts?	☐ No ☐ Yes ☐ Unknown
2a. *If yes,* are they worn to improve reading vision?	☐ No ☐ Yes ☐ Unknown
2b. *If yes,* are they worn to improve distance vision?	☐ No ☐ Yes ☐ Unknown
3. Has the subject ever had any of the following?	
3a. Cataract Surgery on Right Eye	☐ No ☐ Yes ☐ Unknown
3b. Cataract Surgery on Left Eye	☐ No ☐ Yes ☐ Unknown
Same-Day Retest	
Was this the initial OCTA scan?	☐ No ☐ Yes
If this was the initial OCTA scan, was a retest completed on the same day?	☐ No ☐ Yes
If this patient is participating in the test-retest protocol, please use the "OCTA: Test/Retest" forms below	

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ___ ___/ ___ ___/ ___ __ ___ ___	**Evaluator Initials:** ____ ____ ____
Study Visit:	

OCTA: TEST/RETEST – SAME DAY

If this patient is participating in the test-retest protocol, please use this form to record signal strengths for the same-day test-retest scans

Date of OCTA Scans: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)

Right Eye Dilation

One drop of each of the following should be used in the right eye: Proparacaine 0.5%, Tropicamide 1%, Phenylephrine 2.5%. The drops will burn for a few seconds. Dilation takes 10 minutes. Inform patient that their vision may be temporarily blurred for several hours. If any pain within 24 hours call for evaluation immediately.

☐ Subject's right eye is topically anesthetized with 1-2 drops Proparacaine 0.5%

☐ Subject's right eye is dilated with 1-2 drops of

- ☐ Tropicamide 1%
- ☐ Phenylephrine 2.5%
- ☐ Other (specify): _____

(Note: If subject does not appear well dilated after 10 minutes it is reasonable to administer another drop of each dilating drop)

OCTA Scans

Scans of the right eye should be completed first, then the left eye. For each eye, perform the "Angiography 3x3 mm" scans first, followed by the "Optic Disc Cube 200x200" scans. Only scans of signal strength 8 or higher should be saved. Four repeated scans of each region for each eye should be captured.

Scan Number	Signal Strength
Right Eye Angiography 3x3 mm Scan 1	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Angiography 3x3 mm Scan 2	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Angiography 3x3 mm Scan 3	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Angiography 3x3 mm Scan 4	☐ 8 ☐ 9 ☐ 10 ☐ Not Done

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ___ ___/ ___ ___/ ___ __ ___ ___	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Scan Number	Signal Strength
Right Eye Optic Disc Cube 200x200 Scan 1	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Optic Disc Cube 200x200 Scan 2	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Optic Disc Cube 200x200 Scan 3	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Optic Disc Cube 200x200 Scan 4	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Angiography 3x3 mm Scan 1	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Angiography 3x3 mm Scan 2	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Angiography 3x3 mm Scan 3	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Angiography 3x3 mm Scan 4	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Optic Disc Cube 200x200 Scan 1	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Optic Disc Cube 200x200 Scan 2	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Optic Disc Cube 200x200 Scan 3	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Optic Disc Cube 200x200 Scan 4	☐ 8 ☐ 9 ☐ 10 ☐ Not Done

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ___ ___/ ___ ___/ ___ __ ___ ___	**Evaluator Initials:** ____ ____ ____
Study Visit:	

OCTA: TEST/RETEST – WITHIN 14 DAYS

If this patient is participating in the test-retest protocol, please use this form to record signal strengths for the test-retest scans completed within 14 days of the baseline scans

Date of OCTA Scans: __ __ / __ __ / __ __ __ __ (MM/DD/YYYY)

Right Eye Dilation

One drop of each of the following should be used in the right eye: Proparacaine 0.5%, Tropicamide 1%, Phenylephrine 2.5%. The drops will burn for a few seconds. Dilation takes 10 minutes. Inform patient that their vision may be temporarily blurred for several hours. If any pain within 24 hours call for evaluation immediately.

☐ Subject's right eye is topically anesthetized with 1-2 drops Proparacaine 0.5%

☐ Subject's right eye is dilated with 1-2 drops of

- ☐ Tropicamide 1%
- ☐ Phenylephrine 2.5%
- ☐ Other (specify): _____

(Note: If subject does not appear well dilated after 10 minutes it is reasonable to administer another drop of each dilating drop)

OCTA Scans

Scans of the right eye should be completed first, then the left eye. For each eye, perform the "Angiography 3x3 mm" scans first, followed by the "Optic Disc Cube 200x200" scans. Only scans of signal strength 8 or higher should be saved. Four repeated scans of each region for each eye should be captured.

Scan Number	Signal Strength
Right Eye Angiography 3x3 mm Scan 1	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Angiography 3x3 mm Scan 2	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Angiography 3x3 mm Scan 3	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Angiography 3x3 mm Scan 4	☐ 8 ☐ 9 ☐ 10 ☐ Not Done

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: __ __ __ __ __ __ __ __ __ __	**Subject Initials:** ____ ____ ____
Visit Date: ___ ___/ ___ ___/ ___ __ ___ ___	**Evaluator Initials:** ____ ____ ____
Study Visit:	

Scan Number	Signal Strength
Right Eye Optic Disc Cube 200x200 Scan 1	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Optic Disc Cube 200x200 Scan 2	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Optic Disc Cube 200x200 Scan 3	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Right Eye Optic Disc Cube 200x200 Scan 4	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Angiography 3x3 mm Scan 1	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Angiography 3x3 mm Scan 2	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Angiography 3x3 mm Scan 3	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Angiography 3x3 mm Scan 4	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Optic Disc Cube 200x200 Scan 1	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Optic Disc Cube 200x200 Scan 2	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Optic Disc Cube 200x200 Scan 3	☐ 8 ☐ 9 ☐ 10 ☐ Not Done
Left Eye Optic Disc Cube 200x200 Scan 4	☐ 8 ☐ 9 ☐ 10 ☐ Not Done

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

HOLLINGSHEAD INDEX

1 – Major Professionals/ Higher Executives/ Proprietors of Large Concerns
Administrator of Business
Architects
Bank Presidents
Business Owners
Certified Public Accountant
Chief Executive/CEO, CFO, COO
Clergy
Commissioned Officers in the Military
Dentists
Economists
Engineers/ Masters level and above
Executive Vice President
Lawyers/ Judges
Major Contractors
Physicians
President of a Large Company
Professor/ University Teachers
Psychologists
Research Scientists/ PhD
Veterinarians
VP of Large Business
Other/unknown major professional etc.

2 – Lesser Professionals/ Business Managers of Medium-Sized Businesses
Accountants
Advertising Executives
Art Director
Branch Managers
Building Contractors
Business Managers
Chiropractors
Computer Programmer
Database Developer
Engineers- no advanced degree
Executive Managers
Farm Owners
Furniture Business
Gallery Instructor- Museum, Art gallery
Government Officials
Jewelers
Labor Relations Consultant
Librarians
Manufacturing Owners
Mathematician
Musicians
Nurses
Office Managers
Opticians
Personnel Managers

Pharmacists
Police Chief/ Sheriff
Postmaster
Production Managers/ TV/ Radio
Public Health Officers
Purchasing Managers
Real Estate Brokers
Research Assistants
Sales Engineers
Sales Managers
School Guidance Counselor
Social Workers
Teachers/ Elementary & High School
Theatre Owners
Other or unknown lesser professional etc.

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

3 – Administrative Personnel, Small Business Owners, Minor Professionals
Actors
Administrative Assistants
Advertising Agents
Artists
Auto Claims Supervisor
Bakers
Beauty Shop Owners
Chefs
Chief Clerks
Clerk- not professionally trained
Court Reporters
Credit Managers
Department Store Manager
Deputy Sheriffs
Dispatchers
Federal and State Government Officials
Florists
Funeral Directors
Government Officials
Insurance Agents
Laboratory Assistants
Landscape Planners
Mechanical Inspector
Military NCO/Sgts
Morticians
Newspaper/ TV Reporters
Nutritionist
Oral Hygienists
Photographers
Piano Teachers
Plumbers
Quality Control
Radio/ TV Announcers
Real Estate Agents
Restaurant Owners
Sales Representatives
Service Managers
Small Business Owners
Store Managers
Surveyors
Title Searchers
Tool Designers
Traffic Managers
Travel Agents
Veterinary Assistant
Yard Masters/ Rail Road
Other or unknown admin etc.

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

4 – Clerical and Sales Workers, Technicians, Owners of Little Businesses
Bank Tellers
Bill Collectors
Bookkeepers
Clerk
Claims Examiners
Dental Technician
Draftsman
Driving Teacher
Factory Supervisors
Farmers
Flower Shop Worker
Human Resource Interviewer
Laboratory Technicians
Medical Secretary
Newsstand Operator
Post Office Clerk
R.R. Conductors
Railroad Train Engineers
Retail Clerks
Route Managers
Sales
Sales Clerks
Secretaries/ Stenographers
Shipping Clerks
Tailor
Tax Clerks
Telephone Company Worker
Telephone Operators
Timekeepers
Toll Collectors
Tower Operators
Truck Dispatchers

Typists
Utility Worker
Warehouse Clerks
Window Store Trimmers
Other or unknown clerical etc.

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

5 – Skilled Manual Employees
Auto Body Repairs
Barbers
Blacksmiths
Boiler Repairmen
Bookbinders
Brewers
Bulldozer Operators
Cabinet Makers
Carpenters
Cement Layers/ Finishers
Cheese Makers
Construction Foreman
Diemakers
Electricians
Engravers
Exterminators
Firemen
Gardner's/ Landscape
Glassblowers
Glaziers
Gun Smiths
Hair Stylists
Home Repairmen
Kitchen Workers/ Cooks
Locksmiths
Machinists
Mailmen

Maintenance Foreman
Masons
Mechanics
Millwrights
Painters
Paperhangers
Patrolmen
Piano Builders
Piano Tuners
Plumbers
Policemen
Postmen
Printers
Radio/ TV Maintenance
Rail Road Brakeman
Repair
Sheet metal Workers
Ship smiths
Shoe Repairmen
Tile Layers
Tool Makers
Upholsterers
Utility Linemen
Watchmakers
Weavers
Welders
Other or unknown skilled manual etc.

Subject Number: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	**Subject Initials:** ____ ____ ____
Visit Date: ____ ____/ ____ ____/ ____ ____ ____ ____	**Evaluator Initials:** ____ ____ ____
Study Visit:	

6 – Machine Operators and Semiskilled Employees
Apprentices (Electrician/Printers/etc.)
Assembly Line Workers
Bartenders
Building Superintendent
Bus Drivers
Cab/ Taxi Drivers
Cashiers
Cooks- Short Order
Delivery men
Dry Cleaning Pressers
Elevator Operators
Enlisted Military Personnel
Factory Machine Operators
Factory Workers
Foundry Workers
Garage and Gas Station Assistants
Greenhouse Workers
Guards, Security Watchmen
Housekeepers
Machine Operators and semiskilled
Meat Cutters/ Packers
Meter Readers
Oil Delivery Men
Practical Nurses
Pump Operators
Receivers and Checkers
Roofers
Seamstresses
Signal Men- Rail Road
Testers
Trucker Driver
Waiters/ Waitresses
Wine Bottlers
Wood Workers
Wrappers- Stores and Factories
Other or unknown semi-skilled manual etc.

7 – Unskilled Employees
Amusement Park Workers
Cafeteria Workers
Car Cleaners
Construction Laborers
Dairy Workers
Deck Hands
Domestics
Farm Helpers
Fishermen
Freight Handlers
Grave Diggers
Homemaker
Hospital Housekeepers
Janitors
Junk/ Recycle Sorters
Laundry Workers
Messengers
Peddlers
Porters
Roofer Laborers
Shoe Shiners
Stagehands
Stock Handlers
Street Cleaners
Unemployed
Unskilled Factory Workers
Unspecified Laborers
Window Cleaners
Woodchoppers
Other or unknown unskilled