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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

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Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

<u>DEMOGRAPHICS AND RELATED ELEMENTS</u>
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: <input type="checkbox"/> Male <input type="checkbox"/> 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? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown
<i>Ask the subject (or co-participant, if necessary) whether the subject considers her/his ethnicity to be Hispanic/Latino</i>

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Study Visit:	

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.*

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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.*

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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.*

MarkVCID Paper CRF Package Completion Guidelines

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.

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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

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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:

- | | |
|------------------------------------|---|
| <input type="checkbox"/> Married | <input type="checkbox"/> Never married (or marriage was annulled) |
| <input type="checkbox"/> Widowed | <input type="checkbox"/> Living as married/domestic partner |
| <input type="checkbox"/> Divorced | <input type="checkbox"/> Unknown |
| <input type="checkbox"/> 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.*

MarkVCID Paper CRF Package Completion Guidelines

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.*

MarkVCID Paper CRF Package Completion Guidelines

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.*

MarkVCID Paper CRF Package Completion Guidelines

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.'

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Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

<u>MEDICAL/NEUROLOGICAL/PSYCHIATRIC HISTORY</u>			
Date of Collection: ____ / ____ / ____ (MM/DD/YYYY)			
HISTORY OF CIGARETTE SMOKING			
	No	Yes	Unknown
1. Has the subject smoked within the last 30 days?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Has the subject smoked more than 100 cigarettes in her/his life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>If No or Unknown, skip to Cardiovascular Disease section</i>			
2a. Total years smoked: ____ [0-87] <input type="checkbox"/> Unknown			
<i>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.</i>			
2b. Average number of packs smoked per day:			
<input type="checkbox"/> 1 cigarette to less than ½ pack			
<input type="checkbox"/> ½ pack to less than 1 pack			
<input type="checkbox"/> 1 pack to less than 1½ packs			
<input type="checkbox"/> 1½ packs to less than 2 packs			
<input type="checkbox"/> 2 packs or more			
<input type="checkbox"/> Unknown			
2c. If the subject has quit smoking, specify that age at which he/she last smoked (i.e., quit): ____ [8-110] <input type="checkbox"/> N/A <input type="checkbox"/> Unknown			
<i>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.</i>			

MarkVCID Paper CRF Package Completion Guidelines

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

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

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

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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) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Other cardiovascular disease (specify): (enter 'N/A' if absent) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Other cardiovascular disease (specify): (enter 'N/A' if absent) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

MarkVCID Paper CRF Package Completion Guidelines

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	_____ <input type="checkbox"/> Unknown	<input type="checkbox"/> Ischemic <input type="checkbox"/> Hemorrhagic <input type="checkbox"/> Stroke type unknown <input type="checkbox"/> TIA with clear ischemic mechanism	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown
Stroke/Acute Vascular Event 2	_____ <input type="checkbox"/> Unknown	<input type="checkbox"/> Ischemic <input type="checkbox"/> Hemorrhagic <input type="checkbox"/> Stroke type unknown <input type="checkbox"/> TIA with clear ischemic mechanism	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown
Stroke/Acute Vascular Event 3	_____ <input type="checkbox"/> Unknown	<input type="checkbox"/> Ischemic <input type="checkbox"/> Hemorrhagic <input type="checkbox"/> Stroke type unknown <input type="checkbox"/> TIA with clear ischemic mechanism	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown
Stroke/Acute Vascular Event 4	_____ <input type="checkbox"/> Unknown	<input type="checkbox"/> Ischemic <input type="checkbox"/> Hemorrhagic <input type="checkbox"/> Stroke type unknown <input type="checkbox"/> TIA with clear ischemic mechanism	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown
Stroke/Acute Vascular Event 5	_____ <input type="checkbox"/> Unknown	<input type="checkbox"/> Ischemic <input type="checkbox"/> Hemorrhagic <input type="checkbox"/> Stroke type unknown <input type="checkbox"/> TIA with clear ischemic mechanism	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

NEUROLOGIC CONDITIONS				
Condition	Absent	Recent/active	Remote/inactive	Unknown
1. Seizures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Traumatic brain injury (TBI)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Include any reported TBI, including mild TBI and TBI without loss of consciousness</i>				
If TBI recent/active or remote/inactive:				
2a. TBI with brief loss of consciousness (< 5 minutes)				
<input type="checkbox"/> No <input type="checkbox"/> Single <input type="checkbox"/> Repeated/multiple <input type="checkbox"/> Unknown				
2b. TBI with extended loss of consciousness (≥ 5 minutes)				
<input type="checkbox"/> No <input type="checkbox"/> Single <input type="checkbox"/> Repeated/multiple <input type="checkbox"/> Unknown				
2c. TBI without loss of consciousness (as might result from military detonations or sports injuries)?				
<input type="checkbox"/> No <input type="checkbox"/> Single <input type="checkbox"/> Repeated/multiple <input type="checkbox"/> Unknown				
<i>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.</i>				
2d. Age at most recent TBI: ____ <input type="checkbox"/> Unknown				
<i>If exact age is unknown, ask the subject and/or co-participant to estimate. If he/she cannot estimate, select Unknown checkbox.</i>				

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

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

MarkVCID Paper CRF Package Completion Guidelines

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2a. If recent/active or remote/inactive, specify abused substance: _____				
<p><i>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.</i></p>				

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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)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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.</i>				
2. Bipolar disorder	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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.</i>				
3. Schizophrenia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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.</i>				
4. Depression				
4a. Active depression in the last two years <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown				
4b. Depression episodes more than two years ago <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown				
<i>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.</i>				

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

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

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

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Study Visit:	

<u>FAMILY HISTORY</u>			
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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</i>			
If yes:			
1a. Any cases with onset before age 55?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1b. Is there a pattern suggestive of an autosomal dominant family history?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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)</i>			
2. ACQUIRED COGNITIVE IMPAIRMENT: Is there a family history in a first degree relative of cognitive impairment or dementia or Alzheimer's disease?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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</i>			

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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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2b. Any report of cases with autopsy confirmation of another cause of dementia?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2c. Any cases with onset before age 65?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2d. Is there a pattern suggestive of an autosomal dominant family history?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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)</i>			
3. If yes to EITHER autosomal dominant questions above (1b, 2d), complete the following:			
3a. Is there a known mutation? <input type="checkbox"/> No <input type="checkbox"/> Yes			
3b. If yes, please indicate which one: <input type="checkbox"/> PSEN1 <input type="checkbox"/> APP <input type="checkbox"/> PSEN2 <input type="checkbox"/> CADASIL <input type="checkbox"/> Other, specify gene if known: _____ Specify mutation if known: _____			
<i>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.</i>			
3c. Does this individual carry the mutation? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown			

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Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

<u>GENERAL PHYSICAL MEASURES</u>			
Were General Physical Measures performed? <input type="checkbox"/> No <input type="checkbox"/> Yes If No, please provide the primary reason: <input type="checkbox"/> Physical problem <input type="checkbox"/> Verbal refusal <input type="checkbox"/> Cognitive/behavior problem <input type="checkbox"/> Other problem (specify): _____ _____			
Date of Collection: ____ / ____ / ____ (MM/DD/YYYY)			
VITAL SIGNS			
1. Blood Pressure Measurement 1: ____ / ____ mmHg	<input type="checkbox"/> Not Done		
Blood Pressure Measurement 2: ____ / ____ mmHg	<input type="checkbox"/> Not Done		
Blood Pressure Measurement 3: ____ / ____ mmHg	<input type="checkbox"/> Not Done		
<i>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.</i>			
2. Pulse: _____ beats/minute	<input type="checkbox"/> Not Done		
<i>If pulse cannot be obtained, skip and select 'Not Done' in the EDC.</i>			
3. Height: _____ . ____ <input type="checkbox"/> cm <input type="checkbox"/> in	<input type="checkbox"/> Not Done		
<i>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.</i>			
4. Weight: _____ . ____ <input type="checkbox"/> kg <input type="checkbox"/> lb	<input type="checkbox"/> Not Done		
<i>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.</i>			
ADDITIONAL PHYSICAL OBSERVATIONS	No	Yes	Unknown
1. With or without corrective lenses, is the subject's vision functionally normal?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Select No if any functional impairment exists (reduced ability to do everyday activities such as reading or watching television).</i>			
2. With or without a hearing aid(s), is the subject's hearing functionally normal?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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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				
<i>Please refer to the MarkVCID Short Physical Performance Battery Training Manual for detailed instructions on the administration of this assessment.</i>				
<p>KEY: If the subject cannot complete any of the following exams, please give the reason by entering one of the following codes:</p> <table style="width: 100%; border: none;"> <tr> <td style="padding: 2px 10px 2px 20px;">95 = Physical problem</td> <td style="padding: 2px 10px 2px 20px;">96 = Cognitive/behavior problem</td> </tr> <tr> <td style="padding: 2px 10px 2px 20px;">97 = Other problem</td> <td style="padding: 2px 10px 2px 20px;">98 = Verbal refusal</td> </tr> </table>	95 = Physical problem	96 = Cognitive/behavior problem	97 = Other problem	98 = Verbal refusal
95 = Physical problem	96 = Cognitive/behavior problem			
97 = Other problem	98 = Verbal refusal			
<table style="width: 100%; border: none;"> <tr> <td style="width: 80%; padding: 2px 0 2px 20px;">1. Balance Test Score: <i>Side-by-side, semi-tandem, tandem:</i></td> <td style="width: 20%; text-align: right; padding: 2px 0 2px 20px;">____ [0-4, 95-98]</td> </tr> </table>	1. Balance Test Score: <i>Side-by-side, semi-tandem, tandem:</i>	____ [0-4, 95-98]		
1. Balance Test Score: <i>Side-by-side, semi-tandem, tandem:</i>	____ [0-4, 95-98]			
<table style="width: 100%; border: none;"> <tr> <td style="width: 80%; padding: 2px 0 2px 20px;">2. Gait Speed Test Score:</td> <td style="width: 20%; text-align: right; padding: 2px 0 2px 20px;">____ [0-4, 95-98]</td> </tr> </table>	2. Gait Speed Test Score:	____ [0-4, 95-98]		
2. Gait Speed Test Score:	____ [0-4, 95-98]			
<table style="width: 100%; border: none;"> <tr> <td style="width: 80%; padding: 2px 0 2px 20px;">3. Chair Stand Test Score:</td> <td style="width: 20%; text-align: right; padding: 2px 0 2px 20px;">____ [0-4, 95-98]</td> </tr> </table>	3. Chair Stand Test Score:	____ [0-4, 95-98]		
3. Chair Stand Test Score:	____ [0-4, 95-98]			

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

<u>NEUROLOGICAL EXAM</u>
<p><i>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.</i></p> <p><i>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.</i></p> <p><i>Please complete the appropriate sections below, using your best clinical judgment in selecting findings that indicate the likely syndrome(s) that is/are present.</i></p>
<p>Was the Neurological Exam performed?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p style="padding-left: 40px;">If No, please provide the primary reason:</p> <p style="padding-left: 40px;"><input type="checkbox"/> Physical problem <input type="checkbox"/> Verbal refusal</p> <p style="padding-left: 40px;"><input type="checkbox"/> Cognitive/behavior problem <input type="checkbox"/> Other problem (specify): _____</p> <p>_____</p>
<p>Date of Collection: ____ / ____ / ____ (MM/DD/YYYY)</p>

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

PARKINSONIAN FEATURES			
Were Parkinsonian signs present? <input type="checkbox"/> No <input type="checkbox"/> Yes			
<i>If any of the parkinsonian signs listed below are present, select Yes. Otherwise, select No and skip to Cerebrovascular Features section</i>			
Parkinsonian Signs: LEFT	No	Yes	Not Assessed
1. Resting tremor - arm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>A definite rest tremor, even if only intermittent, is sufficient to select Yes.</i>			
2. Slowing of fine motor movements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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.</i>			
3. Rigidity - arm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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.</i>			
Parkinsonian Signs: RIGHT	No	Yes	Not Assessed
4. Resting tremor - arm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>A definite rest tremor, even if only intermittent, is sufficient to select Yes.</i>			
5. Slowing of fine motor movements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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.</i>			
6. Rigidity - arm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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.</i>			

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

Parkinsonian Signs	No	Yes	Not Assessed
7. Bradykinesia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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.</i>			
8. Parkinsonian gait disorder	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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.</i>			
9. Postural instability	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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.</i>			

MarkVCID Paper CRF Package Completion Guidelines

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? <input type="checkbox"/> No <input type="checkbox"/> Yes			
<i>If any of the signs consistent with CVD below are present, select Yes; otherwise, select No and skip to Other Findings section.</i>			
Findings consistent with stroke / cerebrovascular disease	No	Yes	Not Assessed
1. Cortical cognitive deficit (e.g., aphasia, apraxia, neglect)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Indicate as present if it is suspected that there is acquired proximal or distal extremity weakness attributable to cerebrovascular ischemia.</i>			
3. Lateralized abnormal reflexes (to include pathologically brisk deep tendon reflexes, Babinski signs, others)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Indicate as present if it is suspected that there are brisk reflexes or increased tone attributable to cerebrovascular ischemia.</i>			
4. Cortical visual field loss	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>This involves homonymous hemianopsia or quadrantanopsia, or cortical blindness, excluding visual field loss due to optic nerve disease or injury.</i>			
5. Somatosensory loss	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>This involves sensory loss due to involvement of the cerebrum or brain stem, excluding sensory loss due to spinal-cord injury or peripheral neuropathy.</i>			

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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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Indicate as present if it is suspected that there is acquired proximal or distal extremity weakness attributable to cerebrovascular ischemia.</i>			
7. Lateralized abnormal reflexes (to include pathologically brisk deep tendon reflexes, Babinski signs, others)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Indicate as present if it is suspected that there are brisk reflexes or increased tone attributable to cerebrovascular ischemia.</i>			
8. Cortical visual field loss	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>This involves homonymous hemianopsia or quadrantanopsia, or cortical blindness, excluding visual field loss due to optic nerve disease or injury.</i>			
9. Somatosensory loss	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>This involves sensory loss due to involvement of the cerebrum or brain stem, excluding sensory loss due to spinal-cord injury or peripheral neuropathy.</i>			

MarkVCID Paper CRF Package Completion Guidelines

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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."</i>			
2. Is magnetic gait apraxia present?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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.</i>			
3. Higher cortical visual problem suggesting posterior cortical atrophy (e.g., prosopagnosia, simultagnosia, Balint's syndrome) or apraxia of gaze	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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 whole (simultanagnosia), difficulty in fixating the eyes (oculomotor apraxia), and inability to move the hand to a specific object by using vision (optic ataxia).</i>			
4. Findings suggestive of progressive supranuclear palsy (PSP), corticobasal syndrome (CBS), or other related disorders	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>If any of the findings below consistent with PSP, CBS, or other related disorders are present, select Yes; otherwise, select No.</i> <ul style="list-style-type: none"> - 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)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Study Visit:	

<u>COGNITIVE DIAGNOSIS</u>				
Date of Evaluation: ____ / ____ / _____ (MM/DD/YYYY)				
SYNDROMIC DIAGNOSIS				
<input type="checkbox"/> Normal Cognition		<input type="checkbox"/> Impaired, Not MCI		
<input type="checkbox"/> MCI		<input type="checkbox"/> Dementia		
<p>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).</p> <p>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:</p> <ul style="list-style-type: none"> • 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)? <p style="text-align: center;">AND</p> <p style="text-align: center;">Impairment in one* or more of the following domains.</p> <ul style="list-style-type: none"> - 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 comporment <p style="text-align: center;">* 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.</p> <p>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</p> <p>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</p>				
Age of Onset: ____ <input type="checkbox"/> Unknown				
	Present	Primary	Contributing	

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PRIMARY ETIOLOGICAL DIAGNOSES	No	Yes			Non-contributing
1. Alzheimer's disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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) Amnesic disorder: The most common syndromic presentation of AD dementia.

(2) Non-amnesic 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

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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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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.*

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	Present		Primary	Contributing	Non-contributing
	No	Yes			
If Present: 2a. Parkinson's disease	<input type="checkbox"/>	<input type="checkbox"/>			

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: <ul style="list-style-type: none"> • Muscular rigidity. • 4- to 6-Hz rest tremor. • Postural instability not caused by primary visual, vestibular, 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): <ul style="list-style-type: none"> • 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.

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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)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p><i>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:</i></p> <ul style="list-style-type: none"> • <i>CLINICAL EVIDENCE of symptomatic stroke (i.e., abrupt onset of focal neurological signs)</i> – <i>OR –</i> • <i>NEUROIMAGING EVIDENCE of one or more of the following:</i> <ul style="list-style-type: none"> – <i>cystic infarcts (large or small)</i> – <i>significant white matter changes (Grade 7–8+ on Cardiovascular Health Study Scale)</i> – <i>intraparenchymal hemorrhage</i> – <i>multiple microbleeds</i> <p><i>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’.</i></p> <p><i>For subjects with cognitive impairment:</i> <i>Indicate whether vascular brain injury is thought to be the Primary cause, a Contributing cause, or a Non-contributing cause of the cognitive impairment.</i></p> <p><i>Select Primary if the subject has one or more of the following:</i></p> <ul style="list-style-type: none"> • <i>a temporal relationship between a symptomatic stroke (confirmed by neuroimaging) and cognitive decline;</i> • <i>imaging evidence of cystic infarction(s) in a cognitive network</i> • <i>cystic infarct (anywhere in the brain), and imaging evidence of extensive confluent white matter changes (WMH Grade 7–8+), and impairment in executive function.</i> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>For subjects with normal cognition:</i> <i>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.</i></p>					

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

3a. Peri-Ventricular Fazekas Extent Grade	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> Unknown/ N/A
3b. Deep Fazekas Extent Grade	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> Unknown/ N/A
3c. Deep Fazekas Lesion Count Grade	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> Unknown/ N/A
<p><i>Peri-Ventricular Fazekas Extent Grade:</i> <i>Grade 0 – No lesions</i> <i>Grade 1 – Caps or pencil-thin lining</i> <i>Grade 2 – Smooth haloing</i> <i>Grade 3 – Irregular WMH extending into DWM</i></p> <p><i>Deep Fazekas Extent Grade</i> <i>Grade 0 – No lesions</i> <i>Grade 1 – Punctate lesions</i> <i>Grade 2 – Beginning confluent lesions</i> <i>Grade 3 – Confluent lesions</i></p> <p><i>Deep Fazekas Lesion Count Grade</i> <i>Grade 0 – No lesions</i> <i>Grade 1 – 1-4 lesions</i> <i>Grade 2 – 5-9 lesions</i> <i>Grade 3 – >9 lesions</i></p>	

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

	Present		Primary	Contributing	Non-contributing
	No	Yes			
4. Traumatic brain injury	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*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**.*

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

	Present		Primary	Contributing	Non-contributing
	No	Yes			
5. Depression	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If Present: 5a. <input type="checkbox"/> Untreated <input type="checkbox"/> Treated with medication and/or counseling					
<i>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.</i>					
	Present		Primary	Contributing	Non-contributing
	No	Yes			
6. Cognitive impairment due to alcohol abuse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If Present: 6a. Current alcohol abuse	<input type="checkbox"/> No		<input type="checkbox"/> Yes	<input type="checkbox"/> Unknown	

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

RELATED ETIOLOGICAL DIAGNOSES	Present	Primary	Contributing	Non-contributing
7. Multiple system atrophy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p><i>Refer to the diagnostic criteria in Gilman et al. (2008) when assessing the presence of multiple system atrophy (MSA).</i></p> <p><i>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.</i></p> <p><i>If MSA is not present, leave all checkboxes for Questions 7 blank/unchecked.</i></p>				
8. Frontotemporal lobar degeneration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p><i>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).</i></p> <p><i>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.</i></p> <p><i>If the subject does not have any of the listed diseases, leave all boxes for Question 8 unchecked.</i></p> <p><i><u>PSP</u>: Use the criteria by Bensimon et al. (2009) to diagnose PSP</i></p> <p><i><u>CBD</u>: Refer to diagnostic criteria by Armstrong et al. (2013) when assessing the presence of CBD.</i></p> <p><i><u>FTLD with motor neuron disease</u>: Use the following criteria, adapted from El Escorial revisited: Revised criteria for the diagnosis of amyotrophic lateral sclerosis (Brooks et al., 2000)</i></p> <p><i><u>FTLD NOS</u>: Select Present for Question 8 if FTLD not otherwise specified (NOS) is present</i></p>				

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

	Present	Primary	Contributing	Non-contributing
9. Essential tremor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p><i>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.</i></p> <p>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.</p> <p>For subjects with normal cognition: If the subject has normal cognition but has essential tremor features, select Present and select the Non-contributing box.</p>				
10. Down syndrome	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p><i>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.</i></p> <p><i>If Down syndrome is not present, leave all boxes for Question 10 blank/unchecked. If the subject has normal cognition but has Down syndrome, select Present for Question 10 and select the Non-contributing checkbox.</i></p>				
11. Huntington's disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p><i>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 Question 11 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.</i></p>				
12. Prion disease (CJD, other)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p><i>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 Question 11 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.</i></p>				
13. Hydrocephalus	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p><i>If hydrocephalus is not present, leave all boxes in Question 13 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.</i></p>				

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

	Present	Primary	Contributing	Non-contributing
14. Epilepsy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Refer to the paper by Fisher et al. (2014) for clinical symptoms consistent with epilepsy. If epilepsy is not present, leave all boxes in Question 14 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.</i>				
15. CNS neoplasm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If present: 15a. <input type="checkbox"/> Benign <input type="checkbox"/> Malignant				
<i>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.</i>				
16. Human immunodeficiency virus (HIV)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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 Question 16 blank/unchecked.</i>				

MarkVCID Paper CRF Package Completion Guidelines

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Schizophrenia or other psychosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Anxiety disorder	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Delirium	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Post-traumatic stress disorder (PTSD)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Other psychiatric disease (specify): _____ _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

MarkVCID Paper CRF Package Completion Guidelines

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): _____ _____ _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>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.</i>				
23b. Other substance abuse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23c. Systemic disease/medical illness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23d. Medications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23e. Cognitive impairment NOS: _____ _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

<u>MoCA (MONTREAL COGNITIVE ASSESSMENT)</u>				
<i>Please refer to the MarkVCID Evaluator's Instructions Manual for details instructions on the administration of this assessment</i>				
<p>Was any part of the MoCA administered?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p style="margin-left: 40px;">If No, please provide the primary reason: <input type="checkbox"/> Physical problem <input type="checkbox"/> Verbal refusal</p> <p><input type="checkbox"/> Cognitive/behavior problem <input type="checkbox"/> Other problem (specify): _____</p> <p>_____</p>				
Date of Examination: ____ / ____ / ____ (MM/DD/YYYY)				
Method of Administration: <input type="checkbox"/> In-person <input type="checkbox"/> Video				
<p>Language of test administration:</p> <p><input type="checkbox"/> English</p> <p><input type="checkbox"/> Spanish</p> <p><input type="checkbox"/> Other (specify): _____</p>				
<p>KEY: If the subject cannot complete any of the following exams, please give the reason by entering one of the following codes:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">95 = Physical problem</td> <td style="width: 50%;">96 = Cognitive/behavior problem</td> </tr> <tr> <td>97 = Other problem</td> <td>98 = Verbal refusal</td> </tr> </table>	95 = Physical problem	96 = Cognitive/behavior problem	97 = Other problem	98 = Verbal refusal
95 = Physical problem	96 = Cognitive/behavior problem			
97 = Other problem	98 = Verbal refusal			

MarkVCID Paper CRF Package Completion Guidelines

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

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

13. Abstraction:	____ [0-2, 95-98]
<i>Scores for items 14-16 correspond to the Delayed Recall section on the MoCA worksheet</i>	
14. Delayed recall — No cue: <i>(if not completed, enter reason code and skip to question 17)</i>	____ [0-5, 95-98]
15. Delayed recall — Category cue:	____ [0-5, 95-98]
16. Delayed recall — Recognition:	____ [0-5, 95-98]
<i>Scores for items 17-22 correspond to the Orientation section on the MoCA worksheet</i>	
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]

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

<u>Blind MoCA (MONTREAL COGNITIVE ASSESSMENT)</u>
<i>Please refer to the MarkVCID Evaluator's Instructions Manual for details instructions on the administration of this assessment</i>
<p>Was any part of the Blind MoCA administered?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p style="padding-left: 40px;">If No, please provide the primary reason: <input type="checkbox"/> Physical problem <input type="checkbox"/> Verbal refusal</p> <p><input type="checkbox"/> Cognitive/behavior problem <input type="checkbox"/> Other problem (specify): _____</p> <p>_____</p>
Date of Examination: ____ / ____ / ____ (MM/DD/YYYY)
Method of Administration: <input type="checkbox"/> In-person <input type="checkbox"/> Phone
<p>Language of test administration:</p> <p><input type="checkbox"/> English</p> <p><input type="checkbox"/> Spanish</p> <p><input type="checkbox"/> Other (specify): _____</p>
<p>KEY: If the subject cannot complete any of the following exams, please give the reason by entering one of the following codes:</p> <p style="padding-left: 40px;">95 = Physical problem 96 = Cognitive/behavior problem</p> <p style="padding-left: 40px;">97 = Other problem 98 = Verbal refusal</p>
<i>Score is 'Not Assessed' if any of the Blind MoCA items that contribute to the score are missing (i.e., items 8-14 and 17-22). Items 7, 15, and 16 are not part of the Blind MoCA score calculation; therefore, these items can have missing values (95, 96, 97, or 98). The Blind MoCA Score will still be computed as long as items 8-14, and 17-22 are all non-missing.</i>
<i>Score for item 7 corresponds to the Memory section on the Blind MoCA worksheet</i>
7. Memory — Registration (two trials): _____ [0-10, 95-98]
<i>Scores for items 8-10 correspond to the Attention section on the Blind MoCA worksheet</i>

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/_____	Evaluator Initials: _____
Study Visit:	

8. Attention — Digits:	___ [0-2, 95-98]
9. Attention — Letter A:	___ [0-1, 95-98]
10. Attention — Serial 7s:	___ [0-3, 95-98]
<i>Scores for items 11-12 correspond to the Language section on the Blind MoCA worksheet</i>	
11. Language — Repetition:	___ [0-2, 95-98]
12. Language — Fluency:	___ [0-1, 95-98]
<i>Score for item 13 corresponds to the Abstraction section on the Blind MoCA worksheet</i>	
13. Abstraction:	___ [0-2, 95-98]
<i>Scores for items 14-16 correspond to the Delayed Recall section on the Blind MoCA worksheet</i>	
14. Delayed recall — No cue: <i>(if not completed, enter reason code and skip to question 17)</i>	___ [0-5, 95-98]
15. Delayed recall — Category cue:	___ [0-5, 95-98]
16. Delayed recall — Recognition:	___ [0-5, 95-98]
<i>Scores for items 17-22 correspond to the Orientation section on the Blind MoCA worksheet</i>	
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]

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/_____	Evaluator Initials: _____
Study Visit:	

<u>NEUROPSYCHOLOGICAL TESTING BATTERY</u>
<i>Please refer to the MarkVCID Evaluator's Instructions Manual for details instructions on the administration of this assessment</i>
<p>Was any part of the remainder of the Neuropsychological Testing Battery administered?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p style="margin-left: 40px;">If No, please provide the primary reason: <input type="checkbox"/> Physical problem <input type="checkbox"/> Verbal refusal</p> <p><input type="checkbox"/> Cognitive/behavior problem <input type="checkbox"/> Other problem (specify): _____</p> <p>_____</p>
Date of Examination: ____ / ____ / _____ (MM/DD/YYYY)
<i>Indicate the primary language used when administering the remainder of the tests.</i>
<p>Language of test administration:</p> <p><input type="checkbox"/> English</p> <p><input type="checkbox"/> Spanish</p> <p><input type="checkbox"/> Other (specify): _____</p>

MarkVCID Paper CRF Package Completion Guidelines

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:

- | | |
|--|---------------------------------|
| 94 = Test not administered as part of battery at this session (where applicable) | 96 = Cognitive/behavior problem |
| 95 = Physical 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]

Method of Administration: In-person Video Phone

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]

Method of Administration: In-person Video Phone

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]

MarkVCID Paper CRF Package Completion Guidelines

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]
- Method of Administration: In-person Video Phone

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: ____ [94-98]
- 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: ____ [94-98]
- 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]

MarkVCID Paper CRF Package Completion Guidelines

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: ____ [94-98]
 - 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]
- Method of Administration: In-person Video

MarkVCID Paper CRF Package Completion Guidelines

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)

Method of Administration: In-person Video Phone

Section 1: Standard CDR

<i>Please enter score below:</i>	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

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

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
<i>Please enter score below:</i>	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					

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

Section 2: Supplemental CDR					
<i>Please enter score below:</i>	IMPAIRMENT				
	None - 0	Questionable - 0.5	Mild - 1	Moderate - 2	Severe - 3
9. Behavior, comporment, and personality ____ . ____	Socially appropriate behavior	Questionable changes in comporment, 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

MarkVCID Paper CRF Package Completion Guidelines

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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Have you dropped many of your activities and interests?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Do you feel that your life is empty?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Do you often get bored?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Are you in good spirits most of the time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Are you afraid that something bad is going to happen to you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

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

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

LABORATORY TESTS		
Date of Collection: ____ / ____ / _____ (MM/DD/YYYY)		
<p><i>Only enter test results from labs conducted within the last 3 months. Exception: Serum creatinine value may be collected from existing lab results within one year of the baseline visit. 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.'</i></p> <p><i>If fasting conditions are unknown, mark "not fasting".</i></p> <p><i>All tests denoted with * are required. Cholesterol related labs, blood sugar, and homocysteine should be collected under fasting conditions when possible.</i></p>		
PHYSIOLOGIC MEASURES		
Measure	Fasting	Result
1. HS-CRP	N/A	____ mg/L <input type="checkbox"/> Not Done
2. HbA1c*	N/A	____ mmol/mol <input type="checkbox"/> Not Done
3. Blood Sugar	<input type="checkbox"/> Fasting >8 hours <input type="checkbox"/> Not fasting	____ mmol/L <input type="checkbox"/> Not Done
4. Serum cholesterol*	<input type="checkbox"/> Fasting >8 hours <input type="checkbox"/> Not fasting	____ mg/dL <input type="checkbox"/> Not Done
5. HDL cholesterol*	<input type="checkbox"/> Fasting >8 hours <input type="checkbox"/> Not fasting	____ mg/dL <input type="checkbox"/> Not Done
6. LDL cholesterol*	<input type="checkbox"/> Fasting >8 hours <input type="checkbox"/> Not fasting	____ mg/dL <input type="checkbox"/> Not Done
7. Triglycerides*	<input type="checkbox"/> Fasting >8 hours <input type="checkbox"/> Not fasting	____ mg/dL <input type="checkbox"/> Not Done
8. Homocysteine	<input type="checkbox"/> Fasting >8 hours <input type="checkbox"/> Not fasting	____ mg/dL <input type="checkbox"/> Not Done
9. Serum creatinine*	N/A	____ mg/dL <input type="checkbox"/> Not Done

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

GENETICS	
Have any genetic tests been performed?	<input type="checkbox"/> No <input type="checkbox"/> Yes
If yes:	
APOE genotype:	<input type="checkbox"/> E2/E2 <input type="checkbox"/> E2/E3 <input type="checkbox"/> E2/E4 <input type="checkbox"/> E3/E3 <input type="checkbox"/> E3/E4 <input type="checkbox"/> E4/E4 <input type="checkbox"/> Not Done
Has a GWAS been completed?	<input type="checkbox"/> No <input type="checkbox"/> Yes

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

<u>SAMPLE COLLECTION: CSF COLLECTION</u>
Status: <input type="checkbox"/> Collected <input type="checkbox"/> Not Collected
<p style="text-align: center;">If not collected, reason not collected: _____</p> <p style="text-align: center;">_____</p>
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)
<p>Pre-Centrifugation sample:</p> <p>Appearance: <input type="checkbox"/> Clear <input type="checkbox"/> Cloudy</p> <p>Color: <input type="checkbox"/> Pink <input type="checkbox"/> Other (specify): _____</p> <p style="text-align: center;">_____</p>
Number of 0.25 mL aliquots: ____

MarkVCID Paper CRF Package Completion Guidelines

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 -80° 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): _____

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

<u>SAMPLE COLLECTION: PLASMA COLLECTION</u>
Status: <input type="checkbox"/> Collected <input type="checkbox"/> Not Collected
<p style="text-align: center;">If not collected, reason not collected: _____</p> <p style="text-align: center;">_____</p>
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? <input type="checkbox"/> No <input type="checkbox"/> Yes
Storage temperature: ____ °C

MarkVCID Paper CRF Package Completion Guidelines

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 -80° 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): _____
- _____
- _____

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

<u>SAMPLE COLLECTION: SERUM COLLECTION</u>
Status: <input type="checkbox"/> Collected <input type="checkbox"/> Not Collected
<p style="text-align: center;">If not collected, reason not collected: _____</p> <p style="text-align: center;">_____</p>
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? <input type="checkbox"/> No <input type="checkbox"/> Yes
Storage temperature: ____ °C

MarkVCID Paper CRF Package Completion Guidelines

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 -80° 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): _____

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

<u>SAMPLE COLLECTION: PLATELET POOR PLASMA (PPP) COLLECTION</u>
Status: <input type="checkbox"/> Collected <input type="checkbox"/> 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? <input type="checkbox"/> No <input type="checkbox"/> Yes
Storage temperature: ____ °C

MarkVCID Paper CRF Package Completion Guidelines

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):

MarkVCID Paper CRF Package Completion Guidelines

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 -80° 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): _____

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

<u>IMAGING</u>	
Was an MRI performed at this visit?	<input type="checkbox"/> No <input type="checkbox"/> Yes
If No, please provide reason:	<input type="checkbox"/> Claustrophobia <input type="checkbox"/> Other reason: _____ _____
Date of Imaging: ____ / ____ / ____ (MM/DD/YYYY)	

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

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

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 (<u>excluding</u> blurry vision)? <i>(Mark not applicable if patient has never had their eyes dilated for an eye examination)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.2. Were you told not to get dilated again? <i>(Mark not applicable if patient has never had their eyes dilated for an eye examination)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Do you take any prescription eye drops (excluding artificial tears)?	<input type="checkbox"/>	<input type="checkbox"/>	
OCTA Enrollment			
<i>If the subject answered "Yes" to any of the exclusion criteria above, please indicate that the subject cannot undergo OCTA testing.</i>			
<i>If the subject answered "No" or "N/A" to all of the exclusion criteria above, please indicate that they are enrolled in OCTA testing.</i>			
<i>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.</i>			
<input type="checkbox"/> Subject cannot undergo OCTA testing because of exclusion criteria <input type="checkbox"/> 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			

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

<u>OCTA: INITIAL</u>

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	<input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> Not Done
Right Eye Angiography 3x3 mm Scan 2	<input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> Not Done
Right Eye Angiography 3x3 mm Scan 3	<input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> Not Done
Right Eye Angiography 3x3 mm Scan 4	<input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> 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	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Right Eye Optic Disc Cube 200x200 Scan 2	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Right Eye Optic Disc Cube 200x200 Scan 3	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Right Eye Optic Disc Cube 200x200 Scan 4	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Angiography 3x3 mm Scan 1	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Angiography 3x3 mm Scan 2	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Angiography 3x3 mm Scan 3	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Angiography 3x3 mm Scan 4	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Optic Disc Cube 200x200 Scan 1	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Optic Disc Cube 200x200 Scan 2	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Optic Disc Cube 200x200 Scan 3	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Optic Disc Cube 200x200 Scan 4	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

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

MarkVCID Paper CRF Package Completion Guidelines

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	<input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> Not Done
Right Eye Angiography 3x3 mm Scan 2	<input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> Not Done
Right Eye Angiography 3x3 mm Scan 3	<input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> Not Done
Right Eye Angiography 3x3 mm Scan 4	<input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> 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	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Right Eye Optic Disc Cube 200x200 Scan 2	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Right Eye Optic Disc Cube 200x200 Scan 3	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Right Eye Optic Disc Cube 200x200 Scan 4	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Angiography 3x3 mm Scan 1	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Angiography 3x3 mm Scan 2	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Angiography 3x3 mm Scan 3	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Angiography 3x3 mm Scan 4	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Optic Disc Cube 200x200 Scan 1	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Optic Disc Cube 200x200 Scan 2	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Optic Disc Cube 200x200 Scan 3	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Optic Disc Cube 200x200 Scan 4	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done

MarkVCID Paper CRF Package Completion Guidelines

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	<input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> Not Done
Right Eye Angiography 3x3 mm Scan 2	<input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> Not Done
Right Eye Angiography 3x3 mm Scan 3	<input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> Not Done
Right Eye Angiography 3x3 mm Scan 4	<input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> 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	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Right Eye Optic Disc Cube 200x200 Scan 2	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Right Eye Optic Disc Cube 200x200 Scan 3	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Right Eye Optic Disc Cube 200x200 Scan 4	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Angiography 3x3 mm Scan 1	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Angiography 3x3 mm Scan 2	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Angiography 3x3 mm Scan 3	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Angiography 3x3 mm Scan 4	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Optic Disc Cube 200x200 Scan 1	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Optic Disc Cube 200x200 Scan 2	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Optic Disc Cube 200x200 Scan 3	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done
Left Eye Optic Disc Cube 200x200 Scan 4	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> Not Done

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

<u>SUBJECT DISPOSITION</u>
<i>Fill out this form at the end of each study visit to reflect the subject's participation in the study at that point in time.</i>
<p>What is the status of the subject's involvement in this study?</p> <p style="margin-left: 40px;"> <input type="checkbox"/> The subject continues to be actively followed <input type="checkbox"/> The subject's participation has ended </p>
<p><i>Select "the subject continues to be actively followed" if the subject fully completed the baseline MarkVCID visit and, to the best of your knowledge, will be returning for the next scheduled MarkVCID visit. If the subject was not able to complete this visit, but you are still actively reaching out to them to continue their participation, select "the subject continues to be actively followed." You do not need to fill anything else out on this form at this time.</i></p> <p><i>Select "the subject's participation has ended" if the subject is no longer being actively followed for the MarkVCID study. Proceed to filling out the rest of this form.</i></p>
If the subject's participation has ended:
<p>What was the subject's final visit?</p> <p style="margin-left: 40px;"><input type="checkbox"/> Baseline</p>
<p><i>"Baseline" is the only option for the final visit in this visit. If the subject completed subsequent visits, select "the subject continues to be actively followed" for the question above and do not fill anything else out on this form in this visit. Fill out details about the end of the subject's participation in this study in their final visit.</i></p>

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

Please specify their final disposition:

Subject lost to follow-up

Select this option if, during the baseline visit, the subject was unable to complete the visit, and you have not been able to successfully contact them to schedule a time for them to return to complete the visit. If the subject fully completed the baseline visit, and then became lost-to-follow-up when scheduling the next visit, do not select this option in this visit. Select "the subject continues to be actively followed" for the first question, and then select "Subject lost to follow-up" for this question on the disposition form in the next study visit.

Date subject was last known to be alive: ____ / ____ / ____ (MM/DD/YYYY)

Subject early terminated

Select this option if, during the baseline visit, the subject was unable to complete the visit and their participation in the study was terminated, either directly by the participant (i.e., they withdrew consent or explicitly stated they no longer wished to participate), or by the investigator.

Date participation was terminated: ____ / ____ / ____ (MM/DD/YYYY)

Participation terminated by:

- Subject
- Site investigator

Indicate primary reason for early termination:

- Progression of cognitive impairment
- Incident stroke
- Patient/family no longer willing to undergo study procedures
- Other (specify): _____

If early terminated, has the subject indicated they do not want their data, samples, or imaging retained for future use in the study: Yes No

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

Please specify their final disposition (continued):

Subject died

Select this option if, prior to completing the baseline MarkVCID visit, the subject died. If the subject completed the baseline visit and you are contacting them to schedule their next visit and are informed at that time that the subject died, do not select this option in this visit. Select "the subject continues to be actively followed" for the first question, and then select "Subject died" for this question on the disposition form in the next study visit.

Date of death: ____ / ____ / _____ (MM/DD/YYYY)

Cause of/major contributor to death:

- Progression of cognitive impairment
- Incident stroke
- Other (specify): _____

How was this information obtained?

- Subject's family
- Medical records
- Other (specify): _____

Was an autopsy performed? Yes No Unknown

If yes, has a copy of the autopsy report been obtained? Yes No

Based on the autopsy report, was the subject demented at time of death (clinical impression e.g. cognitive impairment)? Yes No

Please copy and paste the autopsy report summary into the EDC, as well as the name and email address of a site contact to request the full autopsy report.

MarkVCID Paper CRF Package Completion Guidelines

Subject Number: _____	Subject Initials: _____
Visit Date: ____/____/____	Evaluator Initials: _____
Study Visit:	

Please specify their final disposition (continued):

Other (specify): _____

Select this option if the subject's participation in the study ended prior to completing the baseline MarkVCID visit, but none of the options above are applicable. If unsure about how to classify a specific instance, contact the Coordinating Center for further guidance.

Date participation ended: ____ / ____ / ____ (MM/DD/YYYY)

Comments: _____

MarkVCID Paper CRF Package Completion Guidelines

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.

MarkVCID Paper CRF Package Completion Guidelines

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.

MarkVCID Paper CRF Package Completion Guidelines

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.

MarkVCID Paper CRF Package Completion Guidelines

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.

MarkVCID Paper CRF Package Completion Guidelines

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