


































Study Form Files included:

-  CRF 01 Demographics.pdf
-  CRF 03 REVISED CAPS DSM V.pdf
-  CRF 04 MINI Summary_V201272015'.pdf
-  CRF 05 Suitability to Have a Dog Checklist_v4 11302015.pdf
-  CRF 07 WHODAS.pdf
-  CRF 08 PCL 5.pdf
-  CRF 09 PittsburghSleep.pdf
-  CRF 10 VR-12.pdf
-  CRF 11 CSSRS V1_1.pdf
-  CRF 12 PHQ9.pdf
-  CRF 13 DAR.pdf
-  CRF 14 Non VA Outpatient and Inpatient Care_V1.1.pdf
-  CRF 15 WPAI_GHPV2.pdf
-  CRF 16 Inclusion-Exclusion_V301242017.pdf
-  CRF 17 Medication Log_V2.1.pdf
-  CRF 18 Payment Log_3.pdf
-  CRF 19 Post Pairing Eval_V2_12_22_2014.pdf
-  CRF 20 Veteran and Service Dog Visit Report_v3_03012017.pdf
-  CRF 21 Dog Related Questions_V5_1_04162015.pdf
-  CRF 22 - Intervention Discontinuation Form.pdf
-  CRF 23 Veterinary Checklist_V5_1_05252016.pdf
-  CRF 24 Study CompletionTerminationV3.pdf
-  CRF 24a Final Interview Service Dogs V2.pdf
-  CRF 24b Final Interview Emotional Support Dogs V2.pdf
-  CRF 24c Final Interview Dog Trainer Evaluation V1.pdf
-  CRF 25 Protocol Deviation.pdf
-  CRF 26 Adverse Events.pdf
-  CRF 26a Adverse Events for Dog.pdf
-  CRF 27 Serious Adverse Events_KOUpdate.pdf
-  CRF 27a Serious Adverse Events for Dogs_KOChanges.pdf
-  CRF 28 SAE Follow-Up.pdf
-  CRF 28a SAE Follow-Up for dogs.pdf
-  CRF 86 Revised IC Confirmation.pdf

Form 01 - Demographics



DataFax #004

Plate #011

Visit #001

SITE NO.	PARTICIPANT ID	ALPHA CODE	DATE OF VISIT		
[][]	[][][][]	[][][][]	[][]	[][]	[][][][]
			<i>Month</i>	<i>Day</i>	<i>Year</i>

FORM 01 - Demographics

Complete this form for all participants at the qualifying visit.

Demographic Information

Date of birth: [][] [][] [][][][]

Month Day Year

Male Female

1. Gender (at birth)..... [] []

2. Marital Status:

- | | |
|--|--|
| <input type="checkbox"/> Married/Civil Union/Partnership | <input type="checkbox"/> Never Married |
| <input type="checkbox"/> Co-habiting | <input type="checkbox"/> Divorced |
| <input type="checkbox"/> Widowed | <input type="checkbox"/> Separated |

3. Ethnicity:

- | | |
|---|--|
| <input type="checkbox"/> Hispanic, or Latino | <input type="checkbox"/> Unknown/not given |
| <input type="checkbox"/> Not Hispanic or Latino | |

4. Race: *(Select all that apply)*

- | | |
|---|---|
| <input type="checkbox"/> American Indian, or Alaskan Native | <input type="checkbox"/> Native Hawaiian, or other Pacific Islander |
| <input type="checkbox"/> Asian | <input type="checkbox"/> White |
| <input type="checkbox"/> Black, or African-American | <input type="checkbox"/> Unknown |
| | <input type="checkbox"/> Other, specify _____ |

5. Years of Formal Education *(Mark 'X' for highest level)*

- | | |
|--|---|
| <input type="checkbox"/> Less than High School Diploma | <input type="checkbox"/> Associates Degree |
| <input type="checkbox"/> High School Diploma/GED | <input type="checkbox"/> Bachelors Degree |
| <input type="checkbox"/> Some College Credit | <input type="checkbox"/> Masters Degree |
| | <input type="checkbox"/> Ph.D. or Professional Degree |

Form 01 Demographics



DataFax #004

Plate #012

Visit #001

<i>SITE NO.</i>	<i>PARTICIPANT ID</i>	<i>ALPHA CODE</i>
[][]	[][][][]	[][][][]

6. When did the participant serve? (Mark 'X' for all that apply)

- | | | |
|---|--|--|
| <input type="checkbox"/> World War I | <input type="checkbox"/> Gulf War | <input type="checkbox"/> Peace time |
| <input type="checkbox"/> World War II | <input type="checkbox"/> Balkans conflict | <input type="checkbox"/> Other war/conflict, specify _____ |
| <input type="checkbox"/> Korean conflict | <input type="checkbox"/> Afganistan conflict | |
| <input type="checkbox"/> Vietnam conflict | <input type="checkbox"/> Iraq conflict | |

7. In what branch of service did the participant serve? (Mark 'X' for all that apply)

- | | | | |
|-------------------------------|------------------------------------|--|---|
| <input type="checkbox"/> Army | <input type="checkbox"/> Air Force | <input type="checkbox"/> Coast Guard | <input type="checkbox"/> National Guard (active duty) |
| <input type="checkbox"/> Navy | <input type="checkbox"/> Marines | <input type="checkbox"/> Merchant Marine | |

8. Did the participant serve outside the United states? No Yes

9. Did the participant serve in a combat area? No Yes

10. Do you have:

a) Hearing Impairment? No Yes

b) Visual Impairment? No Yes

c) Mobility Impairment? No Yes

d) If 'Yes' to any question above, please describe, include how long impairment been present?



SITE NO.
 PARTICIPANT ID
 ALPHA CODE

11. How often do you take a walk outside?

- Never
 One or two times a week
 At least once a day
 More than once a day

12. What are your typical activities/skills?

	I generally feel	Neutral	I generally feel	
I am active	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	I am passive
I prefer group activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	I prefer solitary activities
My activities are satisfying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	My activities are frustrating
I seek new activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	My activities are the same
I enjoy learning new skills	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	I do not enjoy learning new skills
I prefer problem solving activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	I prefer simplistic activities

Alternative Therapies: Some examples of alternative therapies are yoga, acupuncture, massage, and meditation.

13. Do you use or participate in alternative therapies to help with PTSD symptoms? No Yes

If no, please skip to question 16.

If yes, please list the activity and how often you use it.

14. If yes, do you pay out of pocket for use of these alternative therapies? No Yes

15. If yes, list how much per month?

Form 01 Demographics



DataFax #004

Plate #014

Visit #001

SITE NO.	PARTICIPANT ID	ALPHA CODE
□ □ □	□ □ □ □	□ □ □ □

16. Which statement(s) best describes your work status for the last 3 months (Mark 'X' for all that apply)?

- Working, part or full time (please answer 16a below)
- Student, full-time Student, part-time
- Homemaker Retired, but not because of disability
- Volunteer, full-time Volunteer, part-time
- Disabled: unable to work because of physical disability
- Disabled: unable to work because of mental health status
- Unemployed and not seeking work Unemployed and actively seeking work
- Other: please specify _____

a. If you worked during the last 3 months, please provide the average number of hours worked per week: □ □ □

17. Your current approximate income per year is (do not include spouse or other household income sources):

- Less than \$10,000 \$60,000 - \$70,000
- \$10,001 - \$20,000 Greater than \$70,000
- \$20,001 - \$30,000
- \$30,001 - \$40,000
- \$40,001 - \$50,000
- \$50,001 - \$60,000

Form Completed By: _____ Date: _____ □

Investigator's Signature: _____ Date: _____ □



DataFax #004

Plate #302

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

	Sev	Sx (Sev ≥ 2)?
(11) D4 - Persistent negative emotional state	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
(12) D5 - Diminished interest or participation in activities	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
(13) D6 - Detachment or estrangement from others	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
(14) D7 - Persistent inability to experience positive emotions	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
<i>D subtotals</i>	<input type="checkbox"/> <input type="checkbox"/>	# D Sx = <input type="checkbox"/>

E. Arousal and reactivity symptoms (need 2 for diagnosis)	Past Month
--	-------------------

	Sev	Sx (Sev ≥ 2)?
(15) E1 - Irritable behavior and angry outbursts	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
(16) E2 - Reckless or self-destructive behavior	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
(17) E3 - Hypervigilance	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
(18) E4 - Exaggerated startle response	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
(19) E5 - Problems with concentration	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
(20) E6 - Sleep disturbance	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
<i>E subtotals</i>	<input type="checkbox"/> <input type="checkbox"/>	# E Sx = <input type="checkbox"/>

PTSD Totals	Past Month
--------------------	-------------------

	Total Sev	Total # Sx
<i>Sum of subtotals (B+C+D+E)</i>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

F. Duration of disturbance	Current
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(22) Duration of disturbance ≥ 1 month?	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
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DataFax #004

Plate #303

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

G. Distress or impairment (need 1 for diagnosis)	Past Month	
	Sev	Cx (Sev ≥ 2)?
(23) Subjective distress	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
(24) Impairment in social functioning	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
(25) Impairment in occupational functioning	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
<i>G subtotals</i>	<input type="checkbox"/> <input type="checkbox"/>	# G Cx = <input type="checkbox"/>

Global ratings	Past Month
(26) Global validity	<input type="checkbox"/>
(27) Global severity	<input type="checkbox"/>
(28) Global improvement	<input type="checkbox"/>

Dissociative symptoms (need 1 for subtype)	Past Month	
	Sev	Sx (Sev ≥ 2)?
(29) 1 -- Depersonalization	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
(30) 2 -- Derealization	<input type="checkbox"/>	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
<i>Dissociative subtotals</i>	<input type="checkbox"/> <input type="checkbox"/>	# Diss Sx = <input type="checkbox"/>

PTSD diagnosis	Past Month
PTSD PRESENT - ALL CRITERIA (A - G) MET?	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
With dissociative symptoms	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)
(21) With delayed onset (≥ 6 months)	<input type="checkbox"/> NO (0) <input type="checkbox"/> YES (1)

Investigator's Signature: _____ Date: _____

Form 04- MINI Summary



DataFax #004

Plate #042

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

	Time Frame	Meets Criteria	Primary Diagnosis
J1. SUBSTANCE USE DISORDER (Non-Alcohol)	Past 12 Months	<input type="checkbox"/>	<input type="checkbox"/>
K. Psychotic Disorders	Lifetime	<input type="checkbox"/>	<input type="checkbox"/>
	Current	<input type="checkbox"/>	
K1. Mood Disorder with Psychotic Features	Lifetime	<input type="checkbox"/>	<input type="checkbox"/>
K2. Mood Disorder with Psychotic Features	Current	<input type="checkbox"/>	<input type="checkbox"/>
N. GENERALIZED ANXIETY DISORDER	Current (Past 6 Months)	<input type="checkbox"/>	<input type="checkbox"/>

Identify the Primary Diagnosis by Checking the Appropriate Check Box.
 (Which problem troubles you the most or dominates the others or came first in the natural history?)

Form Completed By: _____ Date: _____

Investigator's Signature: _____ Date: _____

Form 05 - Suitability to Have A Dog Checklist



DataFax #004

Plate #052

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

b) If no, when will the conversation happen? _____

8. Has the Veteran spoken to everyone he/she lives with about letting a dog work for him/her (service dog) or bonded strictly to him/her (emotional support dog)?
 No Yes N/A

a) If no, ask when that conversation will happen _____

9. Describe household: Constant Noise, excitement, always in motion Quiet
 Somewhere in between

10. Does Veteran have a plan for when he/she will exercise dog?
 No Yes

a) If yes, describe plan: _____

b) If yes, specify number of minutes each day:

c) If no, talk to Veteran about the importance of dogs getting exercise; develop plan.

11. Is the Veteran away from home for extended periods of time (e.g. work)?
 No Yes

a) If yes, talk to the Veteran about the importance of being home with the dog; develop plan.

12. Outdoor Space:

	No	Yes	Notes
a. Is it possible to take the dog for a walk in the neighborhood for exercise?*	<input type="checkbox"/>	<input type="checkbox"/>	
b. Is there green space or yard to allow the dog to play outside?*	<input type="checkbox"/>	<input type="checkbox"/>	
<i>If NO, skip to 12d.</i>			
c. If there is a yard, is it fenced?	<input type="checkbox"/>	<input type="checkbox"/>	
d. Is Veteran able to pick up solid waste from dog?	<input type="checkbox"/>	<input type="checkbox"/>	
e. Is there a place to appropriately dispose of dog waste?	<input type="checkbox"/>	<input type="checkbox"/>	

*Not an exclusion factor, but should make Veteran aware of the potential benefits.

Form 05 - Suitability to Have A Dog Checklist



DataFax #004

Plate #053

PHASE

VISIT

SITE NO.

PARTICIPANT ID

ALPHA CODE

13. Indoor Space:

	No	Yes	Notes
a. Do all doors to outside close securely?*	<input type="checkbox"/>	<input type="checkbox"/>	
b. Do any of the doors have a dog door? If dog door exists, state size.	<input type="checkbox"/>	<input type="checkbox"/>	
c. Do all cabinet doors at floor level close securely and/or have childproof latches?	<input type="checkbox"/>	<input type="checkbox"/>	
d. Does Veteran keep lid to toilet bowl down?	<input type="checkbox"/>	<input type="checkbox"/>	
e. Does Veteran use sanitizing toilet bowl cleaner?*	<input type="checkbox"/>	<input type="checkbox"/>	
f. Do all trash can lids close securely or kept behind a closet with a secure door?*	<input type="checkbox"/>	<input type="checkbox"/>	
g. Are there places in the house that the Veteran does not want the dog to have access to when the Veteran is home (e.g. baby's room)? <i>If NO, skip to 13i.</i>	<input type="checkbox"/>	<input type="checkbox"/>	
h. If yes, does Veteran have a dog gate/door block to prevent entry into area?*	<input type="checkbox"/>	<input type="checkbox"/>	
i. Are there places in the house that the Veteran does not want the dog to have access to when the Veteran is not at home (e.g. kitchen)? <i>If NO, skip to 13k.</i>	<input type="checkbox"/>	<input type="checkbox"/>	
j. If yes, does Veteran have a dog gate/door block to prevent entry into area?*	<input type="checkbox"/>	<input type="checkbox"/>	
k. It is recommended that the Veteran crate their dog. Is there room for a crate of adequate size in the home?	<input type="checkbox"/>	<input type="checkbox"/>	
l. Does Veteran have a way to keep harmful materials such as laundry, food, medications, cleaning supplies, and fluids for vehicle (e.g. garage) out of reach of a dog? Potentially harmful materials may include chocolate, antifreeze, artificial sweeteners, D-Con or other pest control agents. <i>If YES, skip to 13n.</i>	<input type="checkbox"/>	<input type="checkbox"/>	
m. If not, does Veteran have a plan of how to handle prior to receiving a dog?*	<input type="checkbox"/>	<input type="checkbox"/>	
n. Are there plants in the Veteran's home that may need to be moved, once dog arrives?	<input type="checkbox"/>	<input type="checkbox"/>	

*If no, make recommendations of how to fix so that house would be ok for a dog to live in

Form 05 - Suitability to Have A Dog Checklist



DataFax #004

Plate #054

PHASE

VISIT

SITE NO.

PARTICIPANT ID

ALPHA CODE

No

Yes

14. Does Veteran have mobility issues (use a wheelchair, cane, walker, crutch)?

a. If yes:

1. Specify Device _____

No

Yes

2. Does Veteran understand that dog will not be trained specifically

for the mobility disability?

15. Will a specific harness for the dog be required to accommodate a balance problem?

Yes

No

Potentially

Not Applicable

No

Yes

16. Does Veteran have another type of disability (e.g. hearing or vision) that needs to be considered during the pairing process?

a. If yes, specify: _____

17. Please ask Veteran to explain why he/she wants a Service dog and what the Veteran hopes the dog can do for him/her. _____

18. The sound of a dog barking makes you feel (check all that apply):

Nervous

Anxious

Excited

Angry

Other: -- If other, state the feeling: _____

Form Completed By: _____ Date: _____

Dog Trainer's Signature: _____ Date: _____

Investigator's Signature: _____ Date: _____



DataFax #004

Plate #072

PHASE VISIT

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SITE NO.

--	--	--

PARTICIPANT ID

--	--	--	--

ALPHA CODE

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c. Self care		None	Mild	Moderate	Severe	Extreme or cannot do
D3.1	<u>Washing your whole body?</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D3.2	<u>Getting dressed?</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D3.3	<u>Eating?</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D3.4	<u>Staying by yourself for a few days?</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

d. Getting along with people		None	Mild	Moderate	Severe	Extreme or cannot do
D4.1	<u>Dealing with people you do not know?</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D4.2	<u>Maintaining a friendship?</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D4.3	<u>Getting along with people who are close to you?</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D4.4	<u>Making new friends?</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D4.5	<u>Sexual activities?</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

e. Life Activities		None	Mild	Moderate	Severe	Extreme or cannot do
D5.1	Taking care of your <u>household responsibilities?</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D5.2	Doing most important household tasks <u>well?</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D5.3	Getting all the household work <u>done</u> that you needed to?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D5.4	Getting your household work done as <u>quickly</u> as needed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



DataFax #004

Plate #073

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

If you work (paid, non-paid, self-employed) or go to school, complete questions D5.5-D5.8, below.

Otherwise, skip to D6.1.

Because of your health condition, in the past 30 days, how much difficulty did you have in:		None	Mild	Moderate	Severe	Extreme or cannot do
D5.5	Your day-to-day <u>work/school</u> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D5.6	Doing your most important work/school tasks <u>well</u> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D5.7	Getting all the work <u>done</u> that you need to do?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D5.8	Getting your work done as <u>quickly</u> as possible?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

f. Participation in society		None	Mild	Moderate	Severe	Extreme or cannot do
D6.1	How much of a problem did you have in <u>joining in community activities</u> (for example, festivities, religious or other activities) in the same way as anyone else can?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D6.2	How much of a problem did you have because of <u>barriers or hindrances</u> in the world around you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D6.3	How much of a problem did you have <u>living with dignity</u> because of the attitudes and actions of others?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D6.4	How much <u>time</u> did <u>you</u> spend on your health condition, or its consequences?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D6.5	How much have <u>you</u> been <u>emotionally affected</u> by your health condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D6.6	How much has your health been a <u>drain on the financial resources</u> of you or your family?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D6.7	How much of a problem did your <u>family</u> have because of your health problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D6.8	How much of a problem did you have in doing things <u>by yourself</u> for <u>relaxation or pleasure</u> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



DataFax #004

Plate #074

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

		Record Number of Days
H1	Overall in the past 30 days, <u>how many days</u> were these difficulties present?	<input type="checkbox"/> <input type="checkbox"/>
H2	In the past 30 days, for how many days were you <u>totally unable</u> to carry out your usual activities or work because of any health condition.	<input type="checkbox"/> <input type="checkbox"/>
H3	In the past 30 days, not counting the days that you were totally unable, for how many days did you <u>cut back</u> or <u>reduce</u> your usual activities or work because of any health condition?	<input type="checkbox"/> <input type="checkbox"/>

Form Reviewed By: _____ Date: _____

Investigator's Signature: _____ Date: _____



DataFax #004

Plate #082

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

	Not at all	A little bit	Moderately	Quite a bit	Extremely
8. Trouble remembering important parts of the stressful experience?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Having strong negative beliefs about yourself, other people, or the world (for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Blaming yourself or someone else for the stressful experience or what happened after it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Having strong negative feelings such as fear, horror, anger, guilt or shame?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Loss of interest in activities that you used to enjoy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Feeling distant or cut off from other people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Trouble experiencing positive feelings (for example, being unable to feel happiness or have loving feelings for people close to you)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Irritable behavior, angry outbursts, or acting aggressively?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Taking too many risks or doing things that could cause you harm?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Being "superalert" or watchful or on guard?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Feeling jumpy or easily startled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Having difficulty concentrating?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Trouble falling or staying asleep?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Form Reviewed By: _____ Date: _____

Investigator's Signature: _____ Date: _____



DataFax #004

Plate #091

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE DATE OF ASSESSMENT
 Month Day Year

FORM 09 - Pittsburgh Sleep Quality Index (PSQI)

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please mark one answer for all questions.

During the past month,

1. When do you usually go to bed? : *am pm*

2. How long (in minutes) has it usually taken you to fall asleep each night?

3. What time have you usually gotten up in the morning? : *am pm*

4. How many hours of actual sleep did you get at night?
 (This may be different than the number of hours you spent in bed.)

5. During the past month, how often have you had trouble sleeping because you:	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. Cannot get to sleep within 30 minutes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Wake up in the middle of the night or early morning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Have to get up to use the bathroom	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Cannot breathe comfortably	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Cough or snore loudly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Feel too cold	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



DataFax #004

Plate #092

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

5. During the past month, how often have you had trouble sleeping because you:	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
g. Feel too hot	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Have bad dreams	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Have pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Other reason(s), please describe, including how often you have had trouble because of this reason(s): _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Very good	Fairly good	Fairly bad	Very bad
6. During the past month, how would you rate your sleep quality overall?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
7. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
9. During the past month, how often was it a problem for you to keep up enthusiasm to get things done?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

	No bed partner or roommate	Partner/ roommate in other room	Partner in same room, but not same bed	Partner in same bed
10. Do you have a bed partner or roommate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Form Reviewed By: _____ Date: _____

Investigator's Signature: _____ Date: _____



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PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)? (check one on each line)

	No, none of the time	Yes, a little of the time	Yes, some of the time	Yes, most of the time	Yes, all of the time
a. Accomplished less than you would like.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Were limited in the kind of work or other activities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. During the past 4 weeks, how much did **pain** interfere with your normal work (including both work outside the home and housework)? (check one)

Not at all A little bit Moderately Quite a bit Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

6. How much of the time during the past 4 weeks: (check one on each line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a. Have you felt calm and peaceful ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Did you have a lot of energy ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Have you felt downhearted and blue ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. During the past 4 weeks, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)? (check one)

All of the time Most of the time Some of the time A little of the time None of the time



DataFax #004

Plate #103

<i>PHASE</i>	<i>VISIT</i>
<input type="checkbox"/>	<input type="checkbox"/>

<i>SITE NO.</i>	<i>PARTICIPANT ID</i>	<i>ALPHA CODE</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Now, we'd like to ask you some questions about how your health may have changed.

8. Compared to one year ago, how would you rate your **physical health** in general *now*? (check one)

Much better
 Somewhat better
 About the same
 Somewhat worse
 Much worse

9. Compared to one year ago, how would you rate your **emotional problems** (such as feeling anxious, depressed or irritable) *now*? (check one)

Much better
 Somewhat better
 About the same
 Somewhat worse
 Much worse

Form Reviewed By: _____ Date: _____

Investigator's Signature: _____ Date: _____



DataFax #004

Plate #112

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

Since Last Visit	Yes	No
<p>5. Active Suicidal Ideation with Specific Plan and Intent Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out. Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?</p> <p>If yes, describe: _____</p>	<input type="checkbox"/>	<input type="checkbox"/>

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1 - 5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe Ideation (# 1 - 5 from above):

Description of Ideation: _____

	Most Severe
<p>Frequency How many times have you had these thoughts? (1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day</p>	<input type="checkbox"/>
<p>Duration When you have the thoughts, how long do they last? (1) Fleeting - few seconds or minutes (4) 4-8 hours/most of day (2) Less than 1 hour/some of the time (5) More than 8 hours/persistent or continuous (3) 1-4 hours/a lot of time</p>	<input type="checkbox"/>
<p>Controllability Could/can you stop thinking about killing yourself or wanting to die if you want to? (1) Easily able to control thoughts (4) Can control thoughts with a lot of difficulty (2) Can control thoughts with little difficulty (5) Unable to control thoughts (3) Can control thoughts with some difficulty (0) Does not attempt to control thoughts</p>	<input type="checkbox"/>



DataFax #004

Plate #113

PHASE VISIT

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SITE NO.	PARTICIPANT ID	ALPHA CODE

	Most Severe
<p>Deterrents <i>Are there things - anyone or anything (e.g., family, religion, pain of deaths) - that stopped your from wanting to die or acting on thoughts of committing suicide?</i></p> <p>(1) Deterrents definitely stopped you from attempting suicide (2) Deterrents probably stopped you (3) Uncertain that deterrents stopped you (4) Deterrents most likely did not stop you (5) Deterrents definitely did not stop you (0) Does not apply</p>	<input style="width: 30px; height: 30px;" type="checkbox"/>
<p>Reasons for Ideation <i>What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?</i></p> <p>(1) Completely to get attention, revenge or a reaction from others (2) Mostly to get attention, revenge or a reaction from others (3) Equally to get attention, revenge or a reaction from others and to end/stop the pain (4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling) (5) Completely to end or stop the pain (You couldn't go on living with the pain or how you were feeling) (0) Does not apply</p>	<input style="width: 30px; height: 30px;" type="checkbox"/>



DataFax #004

Plate #114

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

SUICIDAL BEHAVIOR

(Check all that apply, so long as these are separate events; must ask about all types)

Since Last Visit	Yes	No
<p>Actual Attempt: A potentially self-injurious act committed with at least some wish to die, <i>as a result of act</i>. Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is any intent/desire to die associated with the act, then it can be considered an actual suicide attempt. There does not have to be any injury or harm, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. Have you made a suicide attempt? Have you done anything to harm yourself? Have you done anything dangerous where you could have died? <i>What did you do?</i> <i>Did you _____ as a way to end your life?</i> <i>Did you want to die (even a little) when you _____?</i> <i>Were you trying to end your life when you _____?</i> <i>Or did you think it was possible you could have died from _____?</i> Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy or get something else to happen)? (Self-injurious Behavior without suicidal intent) If yes, describe: _____ _____</p>	<input type="checkbox"/> <input type="checkbox"/> Total # of Attempts <input type="checkbox"/> <input type="checkbox"/>	
<p>Has subject engaged in Non-Suicidal Self-Injurious Behavior?</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act (<i>if not for that, actual attempt would have occurred</i>). Overdose: Person has pills in hand but stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has a gun pointed towards self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything? If yes, describe: _____ _____</p>	<input type="checkbox"/> <input type="checkbox"/> Total # of Interrupted <input type="checkbox"/> <input type="checkbox"/>	



DataFax #004

Plate #115

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

SITE NO.	PARTICIPANT ID	ALPHA CODE
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Since Last Visit	Yes	No
<p>Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else.</p> <p><i>Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?</i></p> <p>If yes, describe: _____ _____ _____</p>	<input type="checkbox"/> <input type="checkbox"/> Total # of aborted or self-interrupted <input type="checkbox"/> <input type="checkbox"/>	
<p>Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). <i>Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?</i></p> <p>If yes, describe: _____ _____ _____</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Suicidal Behavior Suicidal behavior was present during the assessment period?</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Suicide:</p>	<input type="checkbox"/>	<input type="checkbox"/>



DataFax #004

Plate #116

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

Answer for Actual Attempts Only

Most Lethal Attempt Date:
 Month Day Year

	Enter Code
<p>Actual Lethality/Medical Damage:</p> <p>0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding or major vessel). 3. Moderately severe physical damage; <i>medical</i> hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body, extensive blood loss but can recover; major fractures). 4. Severe physical damage; <i>medical</i> hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death</p>	<input type="checkbox"/>
<p>Potential Lethality: Only Answer if Actual Lethality = 0</p> <p>Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over).</p> <p>0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care</p>	<input type="checkbox"/>

Form Completed By: _____ Date: _____

Investigator's Signature: _____ Date: _____



DataFax #004

Plate #121

PHASE VISIT

SITE NO. PARTICIPANT ID
 ALPHA CODE DATE OF ASSESSMENT
 Month Day Year

FORM 12 - PHQ-9

1. Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	Several Days	More than half of the days	Nearly everyday
a. Little interest or pleasure in doing things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Feeling down, depressed, or hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Trouble falling or staying asleep, or sleeping too much	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Feeling tired or having little energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Poor appetite or overeating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Trouble concentrating on things, such as reading the newspaper or watching television	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Thoughts that you would be better off dead or of hurting yourself in some way	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all Somewhat difficult Very difficult Extremely difficult

Form Reviewed By: _____ Date: _____

Investigator's Signature: _____ Date: _____

FORM 14 - Non-VA Inpatient and Outpatient Care

INSTRUCTIONS: Complete this form at the baseline visit, every three months during the observational phase, at clearing and at the 3, 6, 9, 12, 15 and 18-month post pairing visits.

At the baseline, observational phase and post-pairing visits ask the participant to recall the inpatient and/or outpatient care they are received at the VA and at non-VA facilities during the last 3 months. During the clearing visit, ask the participant to recall the inpatient and/or outpatient care they are received at the VA and at non-VA facilities since their last visit.

Page 2 of the form is a log of Non-VA inpatient stays for the last 3 months. If additional pages are needed, check the box on the bottom of the form indicating an additional form is needed and record the sequential page number on the next page of the form.

Please use the following codes for the Hospital Type:

- 1 = General hospital for medical or surgical care
- 2 = Nursing home or convalescent center
- 3 = Psychiatric or substance abuse facility
- 4 = Other, such as residential rehabilitation, half-way house or domiciliary

Form 14 - Non-VA Outpatient and Inpatient Care



DataFax #004

Plate #141

PHASE VISIT

SITE PARTICIPANT ID ALPHA CODE DATE OF VISIT
 Month Day Year

FORM 14: Non-VA Outpatient and Inpatient Care

1. In the last 3 months (or since your last visit) when you have needed to see a doctor for outpatient care, how often did you use the VA? Select one response.

- I used the VA for all of my outpatient care
- I used the VA for most of my outpatient care
- I used VA and Non-VA providers equally
- I used non-VA providers for most of my outpatient care
- I used non-VA providers for all of my outpatient care

The next questions ask about visits to non-VA health care clinics during the last 3 months (or since your last visit).

2. During the <u>last 3 months</u> , how many times did you visit a non-VA emergency room to get care for yourself? DO NOT include times where you stayed in a non-VA hospital for more than a day.	<input type="checkbox"/> <input type="checkbox"/>	Emergency Room Visits (write 0 if none)
3. During the <u>last 3 months</u> , how many times did you visit a non-VA clinic to get care for yourself? DO NOT include visits to the emergency room or times when you stayed in a non-VA hospital overnight. DO NOT include dental or optometry visits.	<input type="checkbox"/> <input type="checkbox"/>	Clinic Visits (write 0 if none)

4. In the last 3 months (or since your last visit), when you needed to see a doctor for inpatient care, how often did you use the VA? Select one response.

- I used the VA for all of my inpatient care
- I used the VA for most of my inpatient care
- I used VA and Non-VA providers equally
- I used non-VA providers for most of my inpatient care
- I used non-VA providers for all of my inpatient care

5. During the last 3 months (or since your last visit), have you stayed in a non-VA hospital overnight or longer ?

- No (If no, complete header information on next page and obtain signatures then submit)
- Yes (If yes, please continue to page 3 and enter information for each stay in the hospital)

Form 14 - Non-VA Outpatient and Inpatient Care



DataFax #004

Plate #142

SITE
 PARTICIPANT ID
 ALPHA CODE

PHASE VISIT PAGE

Record information for each non-consecutive overnight hospital stay during the last 3 months or since your last visit. Additional pages may be used if more than 3 hospital admissions occurred. If so, please answer 'Yes' to question 3 below and enter the next page number to be used.

Date of Hospital Admission: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>Month Day Year</i>	Hospital Name: _____ City: _____ State: _____
---	--

Number of nights spent in hospital:
 Did hospital stay begin with visit to emergency department? No Yes

Type of Hospital (Enter code):
 If code = 4 (Other), please explain: _____

Date of Hospital Admission: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>Month Day Year</i>	Hospital Name: _____ City: _____ State: _____
---	--

Number of nights spent in hospital:
 Did hospital stay begin with visit to emergency department? No Yes

Type of Hospital (Enter code):
 If code = 4 (Other), please explain: _____

Date of Hospital Admission: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>Month Day Year</i>	Hospital Name: _____ <input type="text"/> <input type="text"/> City: _____ State: _____
---	--

Number of nights spent in hospital:
 Did hospital stay begin with visit to emergency department? No Yes

Type of Hospital (Enter code):
 If code = 4 (Other), please explain: _____

6. Will an additional page be used to record Non-VA Inpatient Care? No Yes → **If Yes**, record the next page number:

Form Completed By: _____ Date: _____

Investigator's Signature: _____ Date: _____



DataFax #004

Plate #152

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

6. During the past seven days, how much did your health problems affect your ability to do your regular daily activities other than work at a job?

By regular activities, we mean the usual activities you do, such as work around the house, shopping, child care, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like. If health problems affected your activities only a little, choose a low number. Choose a high number if health problems affected your activities a great deal.

Consider only how much health problems affected your ability to do your regular daily activities, other than work at a job.

Health Problems had no effect on my daily activities	0	1	2	3	4	5	6	7	8	9	10	Health Problems completely prevented me from doing my daily activities
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	<i>CHECK ONE NUMBER</i>											

WPAI: GH V2.0 (US English)

Reilly MC, Zbrozek AS, Dukes, E: The validity and reproducibility of a work productivity and activity impairment measure. Pharmacoeconomics 1993; 4(5): 353-365.

Form Reviewed By: _____ Date: _____

Investigator's Signature: _____ Date: _____



DataFax #004

Plate #161

Visit #101

SITE NO.
 PARTICIPANT ID
 ALPHA CODE
 DATE OF VISIT

Month Day Year

FORM 16 - Inclusion/Exclusion

This form should be completed for all participants.

INCLUSION / EXCLUSION CRITERIA SUMMARY

Mark (X) for the questions below to indicate that the participant meets the inclusion criteria and does not have any of the exclusion criteria. All boxes should be checked (indicating "YES") for subject to be eligible.

THE PARTICIPANT...	Baseline	Clearing
1. ...is greater than 18 years of age?	<input type="checkbox"/>	
2. ...has provided written informed consent?	<input type="checkbox"/>	
3. ...has provided a referral from the VA Mental Health Provider which documents PTSD diagnosis?	<input type="checkbox"/>	
4. ...has PTSD as a result of any trauma and diagnosed by DSM 5 diagnostic criteria?	<input type="checkbox"/>	
5. ...is enrolled in VA Mental Health and has attended at least one visit in the 90 days prior to consent?	<input type="checkbox"/>	
6. ...agrees to remain in mental health treatment throughout the duration of the study?	<input type="checkbox"/>	<input type="checkbox"/>
7. ...has the ability to adequately care for a dog?	<input type="checkbox"/>	<input type="checkbox"/>
8. ...has a suitable home environment for a dog?	<input type="checkbox"/>	<input type="checkbox"/>
9. ...has a home environment that is accessible by study staff?	<input type="checkbox"/>	<input type="checkbox"/>
10. ...is willing to accept randomization	<input type="checkbox"/>	<input type="checkbox"/>
11. ...willing and able to travel (by air or car) to training site for pairing?	<input type="checkbox"/>	<input type="checkbox"/>
12. ...has someone to care for dog in long-term absence?	<input type="checkbox"/>	<input type="checkbox"/>
13. ...has others in the home that are agreeable to having a dog?	<input type="checkbox"/>	<input type="checkbox"/>



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Plate #162

Visit #101

SITE NO.	PARTICIPANT ID	ALPHA CODE
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

THE PARTICIPANT...	Baseline	Clearing
14. ...Individual has no cats, dogs or other household pets that would threaten the dog-human bonding process?	<input type="checkbox"/>	<input type="checkbox"/>
15. ...has NOT been hospitalized for mental health reasons in the past 6 months?	<input type="checkbox"/>	<input type="checkbox"/>
16. ... DOES NOT have an aggressive behavior that would make it unsafe for a dog?	<input type="checkbox"/>	<input type="checkbox"/>
17. ... HAS NOT BEEN diagnosed with psychoses, delusions, dementia, active alcohol/substance dependence, or moderate to severe TBI?	<input type="checkbox"/>	
18. ... DOES NOT HAVE any active suicide, homicide, cognitive disabilities that would preclude safety of dog and ability to participate in study?	<input type="checkbox"/>	
19. ... DOES NOT have a suicide flag?	<input type="checkbox"/>	
20. ... DOES NOT HAVE any social, mental or physical condition that would prevents Veteran from participating in study?	<input type="checkbox"/>	<input type="checkbox"/>
21. ...is NOT participating in another research trial (unless approval is received for both study PIs)?	<input type="checkbox"/>	<input type="checkbox"/>
22. ... DOES NOT have the National CPRS flag for violent/disruptive behavior?	<input type="checkbox"/>	<input type="checkbox"/>
23. ... DOES NOT HAVE children younger than age 5 in the household for more than 8 hours per day, one day a week or more?	<input type="checkbox"/>	<input type="checkbox"/>
a. If children in the household, list ages of children under 10:		
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		



SITE NO.	PARTICIPANT ID	ALPHA CODE
[][]	[][][][]	[][][][]

24. Was the participant randomized? Yes No

If yes, please answer the questions below:

a. Date of randomization: [][] [][] [][][][]
Month Day Year

- b. Vendor: *Canine Companions for Independence*
 Auburn Research and Technology Foundation (iK9)
 Armed Forces Foundation (K-2 Solutions)

25. Was the participant cleared to be paired with a dog? Yes No

a. If no, indicate reason: _____

Form Completed By: _____ Date: _____

Investigator's Signature: _____ Date: _____

Form 17 - Prior/Concomitant Medications Log

INSTRUCTIONS: List all **Non-VA prescribed Psychiatric and Sleep Medications** taken by the participant from the 30 days **prior** to consent until the Veteran ends their participation in the study.

At each study visit after the day of consent, update medication use. Record the generic name of the medication, the reason the medication was taken, the date the participant started the medication, the dose, route, units, and frequency using the codes below. When the medication is stopped, record the stop date; otherwise mark (X) if continuing.

When dosage, units, and/or frequency change occurs, enter a stop date for the previous dose/frequency and make a new entry on the form for the medication at the new dose/frequency.

Units

01 = Capsule/Tablet	06 = Spray/Squirt
02 = Drop	07 = Tablespoon
03 = Milligram	08 = Teaspoon
04 = Milliliter	09 = Unknown
05 = Puff	10 = Other

Frequency

1 = Once a day	4 = Four times a day
2 = Twice a day	5 = PRN
3 = Three times a day	6 = Other



DataFax #004

Plate #171

PAGE [][] SITE NO. [][][] PARTICIPANT ID [][][][] ALPHA CODE [][][][] DATE COMPLETED
 [][] [][] [][][][]
 Month Day Year

FORM 17 - MEDICATION LOG

Mark (X) in this box if **NO** Non-VA prescribed psychiatric or sleep medications were reported during the entire study

1. Medication Name _____ Reason Taken _____
 Medication Start Date [][] [][] [][][][]
 Medication Stop Date [][] [][] [][][][]
 Dose [][][][] . [][] Units [][] Frequency Mark (X) if continuing medication

2. Medication Name _____ Reason Taken _____
 Medication Start Date [][] [][] [][][][]
 Medication Stop Date [][] [][] [][][][]
 Dose [][][][] . [][] Units [][] Frequency Mark (X) if continuing medication

3. Medication Name _____ Reason Taken _____
 Medication Start Date [][] [][] [][][][]
 Medication Stop Date [][] [][] [][][][]
 Dose [][][][] . [][] Units [][] Frequency Mark (X) if continuing medication

4. Medication Name _____ Reason Taken _____
 Medication Start Date [][] [][] [][][][]
 Medication Stop Date [][] [][] [][][][]
 Dose [][][][] . [][] Units [][] Frequency Mark (X) if continuing medication

• Will an additional page be used to record medications? No Yes

If Yes, record next page number [][]

Form Completed By: _____ Date: _____

Investigator's Signature: _____ Date: _____

Form 18 - Payment Log



DataFax #004

Plate #181

Visit #318

SITE NO.
 PARTICIPANT ID
 ALPHA CODE
 DATE OF COMPLETION

Month Day Year

FORM 18 - Payment Log - Update this log form at every visit and submit to CSPCC at end of subject's participation in trial.

Phase	Visit	Visit Name	Form Completion Payment	Dog Stipend	Number of Purina Coupons
00	01	Screening	<input type="checkbox"/> \$25.00	N/A	N/A
00	02	Baseline	<input type="checkbox"/> \$10.00	N/A	N/A
01	01	Clearing	<input type="checkbox"/> \$25.00	N/A	N/A
01	02	Clearing-Home	<input type="checkbox"/> \$10.00	N/A	N/A
POST PAIRING VISITS					
02	01	1 - week	<input type="checkbox"/> \$10.00	N/A	<input type="checkbox"/>
02	02	2 - week	<input type="checkbox"/> \$10.00	N/A	<input type="checkbox"/>
03	01	1-month	<input type="checkbox"/> \$10.00	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	02	2-month	<input type="checkbox"/> \$10.00	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	03	3-month	<input type="checkbox"/> \$25.00	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	04	4-month	N/A	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	05	5-month	N/A	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	06	6-month	<input type="checkbox"/> \$10.00	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	07	7-month	N/A	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	08	8-month	N/A	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	09	9-month	<input type="checkbox"/> \$25.00	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	10	10-month	N/A	<input type="checkbox"/> \$75.00	<input type="checkbox"/>

Form 18 - Payment Log



DataFax #004

Plate #182

Visit #318

<i>SITE NO.</i>	<i>PARTICIPANT ID</i>	<i>ALPHA CODE</i>
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Phase	Visit	Visit Name	Form Completion Payment	Dog Stipend	Number of Purina Coupons
03	11	11-month	N/A	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	12	12-month	<input type="checkbox"/> \$10.00	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	13	13-month	N/A	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	14	14-month	N/A	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	15	15-month	<input type="checkbox"/> \$25.00	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	16	16-month	N/A	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	17	17-month	N/A	<input type="checkbox"/> \$75.00	<input type="checkbox"/>
03	18	18-month	<input type="checkbox"/> \$10.00	<input type="checkbox"/> \$75.00	<input type="checkbox"/>

Comments/Notes: _____

Form Reviewed By: _____ Date: _____

Investigator's Signature: _____ Date: _____



DataFax #004

Plate #191

PHASE VISIT

--	--	--

SITE NO.	PARTICIPANT ID	ALPHA CODE	DATE OF ASSESSMENT						
□ □ □	□ □ □ □	□ □ □ □	□ □ □ □	□ □	□ □	□ □ □ □	Month	Day	Year

FORM 19 - Post Pairing Evaluation

Emotional Support Dog Service Dog

1. Location of visit (specify place of visit along with additional locations visited - e.g. home and restaurant):

	Yes	No	Not known
Dog's Demeanor - if there are concerns please describe in Question 20.			
2. Did the dog react in a neutral or friendly manner when approached by unfamiliar persons(s)? <i>If No, provide a detailed explanation in Question 20.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Did the dog react in a neutral or friendly manner when approached by another (unfamiliar) dog (SERV or EMOT)? <i>If No, provide a detailed explanation in Question 20.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Did the dog react (bark, chase, or lunge at) to a cat or other small animal? <i>If Yes, provide a detailed explanation in Question 20.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Overall is the dog relaxed and friendly? <i>If No, provide a detailed explanation in Question 20.</i>	<input type="checkbox"/>	<input type="checkbox"/>	
Dog's General Health - if there are any concerns, please describe in Question 21.			
6. Does the dog appear to be well groomed (shiny coat, white teeth, nails trimmed, etc.)? <i>If No, provide a detailed explanation in Question 21.</i>	<input type="checkbox"/>	<input type="checkbox"/>	
7. Does the dog appear to be at an appropriate weight? <i>If No, provide a detailed explanation in Question 21.</i>	<input type="checkbox"/>	<input type="checkbox"/>	
8. Does the dog appear to be physically fit (no difficulty raising, no lameness, shortness of breath, no vomiting or diarrhea, lesions, etc.)? <i>If No, provide a detailed explanation in Question 21.</i>	<input type="checkbox"/>	<input type="checkbox"/>	
Relationship with Veteran - if there are any concerns, please describe in Question 22.			
9. Does the dog stay in a relative heel position? <i>If No, what happens? Provide a detailed explanation in Question 22.</i>	<input type="checkbox"/>	<input type="checkbox"/>	
9b. Is Veteran attentive to dog? <i>If No, what happens? Provide a detailed explanation in Question 22.</i>	<input type="checkbox"/>	<input type="checkbox"/>	



DataFax #004

Plate #192

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

	Yes	No	Not known
10. Is the dog attentive to the Veteran? <i>If No, provide a detailed explanation in Question 22.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Does the dog wander off to other rooms or follow other people? <i>If Yes, provide a detailed explanation in Question 22.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11b. Does Veteran show affection to the Dog? <i>If No, how does Veteran treat the dog? Provide a detailed explanation in Question 22.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Does the dog seek praise and affection from the Veteran? <i>If No, provide a detailed explanation in Question 22.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Training - if there are any concerns, please describe in Question 23.			<input type="checkbox"/>
13. Does the dog respond appropriately when called by the Veteran?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Obedience/Tasks - if there are concerns please describe in Question 24			<input type="checkbox"/>
14. Does the dog consistently perform basic obedience tasks when asked by the Veteran?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a. Sit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Stay	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Down	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Others: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Training - if there are any concerns, please describe in Question 23.			<input type="checkbox"/>
15. Does the dog display any disruptive behaviors (house soiling, barking, chewing on furniture or other items, begging for table food, intrusive behavior, fearful, any type of aggressive behavior, etc.)? <i>If Yes, provide a detailed explanation in Question 23.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Does the Veteran have good control over the dog? <i>If No, provide a detailed explanation in Question 23.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

17. What equipment is the Veteran utilizing to handle the dog? _____



DataFax #004

Plate #193

<i>PHASE</i>	<i>VISIT</i>
<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

<i>SITE NO.</i>	<i>PARTICIPANT ID</i>	<i>ALPHA CODE</i>
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

18. Any concern the dog could be a threat to humans or other animals? Yes No

If yes, explain: _____

19. Any concern regarding the Veteran's mental or physical health or home environment? Yes No

If yes, explain: _____

20. Any concerns regarding the dog's demeanor? Yes No

If yes, explain: _____

21. Any concerns regarding the dog's health? Yes No

If yes, explain: _____

22. Any concerns regarding the relation of dog to Veteran? Yes No

If yes, explain: _____

23. Any concerns regarding the dog's training? Yes No

If yes, explain: _____



DataFax #004

Plate #194

<i>PHASE</i>	<i>VISIT</i>
<input type="checkbox"/>	<input type="checkbox"/>

<i>SITE NO.</i>	<i>PARTICIPANT ID</i>	<i>ALPHA CODE</i>
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

24. What tasks/commands is the Veteran using with their dog?

25. Is additional training needed (and state plan for training)? Yes No

If yes, explain: _____

26. Additional comments or suggestions?

FOR SERVICE DOGS, PLEASE CONTINUE TO THE NEXT PAGE FOR QUESTIONS 27 - 28.

FOR EMOTIONAL SUPPORT DOGS - THE FORM IS COMPLETE. PLEASE FAX TO CSPCC.



DataFax #004

Plate #195

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

SITE NO.	PARTICIPANT ID	ALPHA CODE
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

COMPLETE FOR SERVICE DOGS ONLY

Questions - For all NO responses to question 27, provide a detailed explanation in the comments (Question 28) below.

Yes No*

Training - if there are any concerns, please describe in Question 23.

27. Does the SERV consistently perform the tasks that aid the Veteran?	<input type="checkbox"/>	<input type="checkbox"/>
<hr/>		
a. Task 1: _____	<input type="checkbox"/>	<input type="checkbox"/>
<hr/>		
b. Task 2: _____	<input type="checkbox"/>	<input type="checkbox"/>
<hr/>		
c. Task 3: _____	<input type="checkbox"/>	<input type="checkbox"/>
<hr/>		
d. Task 4: _____	<input type="checkbox"/>	<input type="checkbox"/>
<hr/>		
e. Task 5: _____	<input type="checkbox"/>	<input type="checkbox"/>
<hr/>		

28. Comments: _____

Form Completed By: _____ Date: _____

Dog Trainer's Signature: _____ Date: _____

Investigator's Signature: _____ Date: _____

Form 20 - Veteran and Service Dog Visit Report



DataFax #004

Plate #201

PHASE VISIT APPOINTMENT#

SITE NO.

PARTICIPANT ID.

ALPHA CODE

DATE OF VISIT

Month

Day

Year

FORM 20 - Veteran and Service/Emotional Support Dog Visit Report

1. Study Protocol Visit (e.g., 3, 6, etc.): Yes No

1a. If no, reason for visit: _____

2. Attending Trainer (Full Name): _____

3. Secondary Trainer (Full Name): _____

4. Location of visit: Clinic Home Other, specify _____

5. Summary of reason for visit : _____

6. What was performed to address any problems or challenges experienced by the Veteran: _____

7. Health of pairing (dog's ability to perform, Veteran's ability to handle dog): _____

Form 20 - Veteran and Service Dog Visit Report



DataFax #004

Plate #202

PHASE VISIT APPOINTMENT#

SITE NO.

PARTICIPANT ID.

ALPHA CODE

8. Any concern regarding the Veteran's mental or physical health, or home environment: _____

9. Any concern about the health of the dog: _____

10. Is additional training needed? No Yes

a. If yes, please explain: _____

11. Additional comments or suggestions: _____

Dog Trainer's Signature: _____ Date: _____

Investigator's Signature: _____ Date: _____

Form 20 - Veteran and Service Dog Visit Report



DataFax #004

Plate #203

PHASE VISIT APPOINTMENT#

SITE NO.

PARTICIPANT ID.

ALPHA CODE

No Yes

12. Has a child been introduced to the home after pairing.....

13. Comments _____

Dog Trainer's Signature: _____ Date: _____

Investigator's Signature: _____ Date: _____

Form 21 - Dog Related Questions



DataFax #004

Plate #211

PHASE

VISIT

APPOINTMENT#

SITE NO.

PARTICIPANT ID

ALPHA CODE

DATE OF ASSESSMENT

Month

Day

Year

FORM 21 - Dog Related Questions

1. Study Protocol Visit (e.g., 3, 6, etc.): Yes No

1a. **If No:** (i) Notify National VA Dog Trainer

(ii) Provide summary of interaction (e.g., issues discussed, advice given, plan of action). If the event qualifies as an adverse event, please complete Form 26 or Form 26a.

(iii) Submit form to CSPCC

If Yes (Study Protocol Visit), Please Complete the Remainder of the Form

2. Overall how satisfied are you with your dog?

Not Satisfied Very Satisfied

1 2 3 4 5 6 7 8 9 10

a. Explain your answer to Question 2: _____

3. Has your dog shown any aggressive behavior (growling, snapping, etc.)

to animals, children or other people? Yes No

a. If yes, explain: _____

Form 21 - Dog Related Questions



DataFax #004

Plate #212

PHASE

VISIT

APPOINTMENT#

SITE NO.

PARTICIPANT ID

ALPHA CODE

4. Has your dog shown any friendly behavior towards animals, children or other people? Yes No

a. Tell me about these interactions: _____

5. Is your dog generally well behaved (quiet, easy to control, stays with you, does not jump on or lunge at people?) Yes No

a. If no, please check all that apply:

- Barking
- Hard to handle
- Runs away
- Jumps up

b. In general, how often do these problems occur?

- Seldom
- Most of the time
- All of the time

6. How often does your dog complete the command you ask him/her to do on the first try?

- Never
- Seldom
- Most of the time
- All of the time

7. Does your dog stay in a relative heel position?

- Never
- Seldom
- Most of the time
- All of the time

a. If any response other than "all of the time" is chosen, please explain: _____

8. Are you having trouble crating your dog?

- Yes
- No
- Not Applicable (I do not crate my dog)

9. When out in public does your dog leave food or other items found on the ground?

- Never
- Seldom
- Most of the time
- All of the time

10. Does your dog have problems riding in a vehicle? Yes No

Form 21 - Dog Related Questions



DataFax #004

Plate #213

PHASE

VISIT

APPOINTMENT#

SITE NO.

PARTICIPANT ID

ALPHA CODE

11. Is your dog's activity level appropriate to meet your needs? Yes No

a. If no, explain: _____

12. Is your dog confident when going into new situations? Yes No

a. If no, explain: _____

13. Is your dog confident when going into unfamiliar places? Yes No

a. If no, explain: _____

14. Is your dog eating and drinking normally? Yes No

a. If no, what have you noticed? Have you done anything about this? If so, what? (e.g. notified your veterinarian or a study team member): _____

15. Are there any issues you are having with your dog that have not been addressed? ... Yes No

a. If yes, please describe: _____

Form 21 - Dog Related Questions



DataFax #004

Plate #214

PHASE

VISIT

APPOINTMENT#

SITE NO.

PARTICIPANT ID

ALPHA CODE

16. How has having a dog changed your daily life?

17. What are some things you like about having a dog?

18. What are some things you do not like about having a dog?

19. What is the most important thing your dog does to help you?

20. Since you received your dog, are there any recreational or leisure activities that you are able to do that you were unable to do before receiving your dog? Yes No

a. If yes, please describe these activities: _____

Form 21 - Dog Related Questions



DataFax #004

Plate #215

PHASE

VISIT

APPOINTMENT#

SITE NO.

PARTICIPANT ID

ALPHA CODE

21. Has your partnership with a dog had an impact on your caregiver or significant other? Yes No

a. If yes, please describe the impact on your caregiver or significant other:

22. Is there anything else you want us to know about the bond between you and your dog?

23. Describe how your interactions with other people have changed since receiving your dog:

24. Does your dog do other things that help with your PTSD symptoms? Yes No

a. If yes, describe what the dog does and what symptom it helps: _____

If you have a SERVICE DOG, complete Questions 25 - 28.

Form 21 - Dog Related Questions



DataFax #004

Plate #216

PHASE

VISIT

APPOINTMENT#

SITE NO.

PARTICIPANT ID

ALPHA CODE

25. Has your **service dog** changed your ability to participate in activities (such as dining out, having friends visit, going shopping)?..... Yes No

a. If yes, describe what you feel your dog has done to change your ability to participate:

26. Have you been denied access to a building or place of business because of your **service dog**? Yes No
a. If yes, please describe the type of business and what happened. How was it resolved?

27. Do you use the specific tasks that your **service dog** was trained to do?..... Yes No

a. If yes, please describe which tasks you use most frequently:

28. How often and in what situations do you use the specific tasks your **service dog** was trained to do?

Form Completed by: _____ Date: _____

Dog Trainer's Signature: _____ Date: _____

Investigator's Signature: _____ Date: _____

Form 22 - Intervention Discontinuation (Dog Return) Form



DataFax #004

Plate #222

PHASE

VISIT

SUBMISSION #

SITE NO.

PARTICIPANT ID

ALPHA CODE

4. Was an adverse event (AE) or serious adverse event (SAE) associated with the return of the dog?

 Yes No

4a. If yes, record Form # and AE/SAE #.

Form #:

AE/SAE#:

Form#:

AE/SAE#:

5. Additional Comments:

Form Completed By: _____ Date: _____

Investigator's Signature: _____ Date: _____

Form 23 - Veterinary Checklist



DataFax #004

Plate #231

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE DATE COMPLETED
 Month Day Year

FORM 23 - Veterinary Checklist

Section A. Instructions to Private Veterinarian. Routine veterinarian visits are required by VA every 6 months as seen in the table below. All dogs are covered by complete wellness, medical and surgical insurance, with no co-pay or out-of-pocket expenses by the Veterans. Ask the Veteran for the correct policy number and insurance company. If you have questions about the insurance or clinical aspects of this form, contact Dr. Joan Richerson at 615-574-8198 or Dr. Mike Fallon at 404-732-5471. The VA is particularly focused on ensuring the safety of the dog, the Veteran, and the Veteran's family by monitoring carefully for zoonotic conditions. Please complete this form fully for each 0,6,12 or 17 month scheduled clinic visit and return it immediately. **Please return to the enclosed address.**

Please complete the sections of this form as indicated:

Months after Dog is Received	Complete Section B, Basic Information	Complete Section C, Parasite Screen?	Complete Section D, Physical Examination?	Complete Section E, Veterinarian's comments	Complete Section F, Signature
0 (immediately after receipt)	Yes	Yes	Only as needed	Optional	Yes
6	Yes	Yes	Only as needed	Optional	Yes
12	Yes	Yes	Yes	Optional	Yes
17	Yes	Yes	Only as needed	Optional	Yes

Month 0 (immediately after receipt of dog) 12 months after receipt of dog

1. Which visit is this?

6 months after receipt of dog 17 months after receipt of dog

Section B. Basic Information (Required for all 4 scheduled visits):

2. Dog's Name: _____

3. Dog's Weight: lbs.

4. Microchip number: _____

5. Veterinarian's Name: _____

6. Clinic Name: _____

7. Clinic Phone Number: -- Ext.

Form 23 - Veterinary Checklist



DataFax #004

Plate #232

PHASE VISIT

SITE NO. PARTICIPANT ID ALPHA CODE

Section C. Parasite Screen (Required upon receipt, and at 6, 12, and 17 month visits)

8. Indicate heartworm, flea and tick prevention use. If none are in use, please explain the circumstances (Note: All VA study dogs should be on year-round heartworm, flea, and tick preventatives).

a. Current heartworm, flea, tick medication: _____

b. Note any change in medication, if any: _____

9. Complete the following table:

TESTS	Date Performed MM DD YYYY	Results/Comments
Heartworm Ag test	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Fecal Flotation	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Giardia IDEXX SNAP test	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Sarcoptes/Ringworm evaluation	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Other as ordered by Veterinarian	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	

10. If dog presents with loose stool or diarrhea, check for salmonella and other zoonotic pathogens as are appropriate.

a. Was a stool culture submitted?: Yes No

Form 23 - Veterinary Checklist



DataFax #004

Plate #233

PHASE

VISIT

SITE NO.

PARTICIPANT ID

ALPHA CODE

Section D. Physical Examination (Required at 12 month visit, complete as needed at other times).

TESTS	Date Performed MM DD YYYY	Results/Comments
Ophthalmic exam including intraocular pressure	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Otological Exam	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Dental Exam	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Cardiovascular assessment - auscultation	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Respiratory assessment - auscultation	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Neurological Exam	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Dermatological exam	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Musculoskeletal examination	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Abdominal palpation	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Urogenital exam	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Rectal exam	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	

Form 23 - Veterinary Checklist



DataFax #004

Plate #234

PHASE

VISIT

SITE NO.

PARTICIPANT ID

ALPHA CODE

TESTS	Date Performed MM DD YYYY	Results/Comments
CBC/differential	<input type="text"/>	
Serum chemistry profile including electrolytes	<input type="text"/>	
Urinalysis	<input type="text"/>	

Vaccinations	Date Administered MM DD YYYY	Comments
Rabies (annual or every 3 yrs depending on local requirements)	<input type="text"/>	
Canine distemper virus (every 3 yrs)	<input type="text"/>	
Canine parvovirus (every 3 yrs)	<input type="text"/>	
Canine adenovirus-2 (every 3 yrs)	<input type="text"/>	

Form 23 - Veterinary Checklist



DataFax #004

Plate #235

PHASE VISIT

--	--	--

<i>SITE NO.</i>	<i>PARTICIPANT ID</i>	<i>ALPHA CODE</i>

Recommended non-core vaccinations (if applicable; varies with geographic location and zoonotic disease risk). Please list:	Date Administered <i>MM DD YYYY</i>	Comments								
	<table border="1" style="width: 100%;"> <tr> <td style="width: 15%;"> </td><td style="width: 15%;"> </td><td style="width: 15%;"> </td><td style="width: 15%;"> </td><td style="width: 15%;"> </td><td style="width: 15%;"> </td><td style="width: 15%;"> </td><td style="width: 15%;"> </td> </tr> </table>									
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Section E. Veterinarian's comments (Optional): _____

Section F. Veterinarian's Signature: _____

Date:

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Site Staff Signature: _____ Date: _____

FORM 24 - Study Completion/Termination

Complete this form for all randomized participants upon completion of or termination from the study.

If a participant has had their eligibility status change after randomization but before the clearing visit(s) or after the clearing visit, select the criteria number(s) that the participant did not meet from the list below:

- 01 - participant is under the age of 18
- 02 - participant did not give informed consent
- 03 - referral from the VA mental Health Provider was not provided or was withdrawn.
- 04 - does not have PTSD as diagnosed by DSM 5 diagnostic criteria
- 05 - is not enrolled in VA mental health or has not attended at least 1 visit in the 90 days prior to consent
- 06 - does not agree to remain in mental health treatment throughout the duration of the study
- 07 - does not have the ability to adequately care for a dog
- 08 - does not have a suitable environment for a dog
- 09 - does not have a home environment accessible by study staff
- 10 - is not willing to accept randomization
- 11 - is not willing and able to travel (by car or air) to the training site for pairing
- 12 - does not have someone to care for a dog in long-term absence
- 13 - has other in the home that are not agreeable to having a dog
- 14 - Has cat/dog/other household pet that would threaten the dog-human bonding process
- 15 - has been hospitalized for mental health reason in past 6 months
- 16 - has an aggressive behavior that makes it unsafe for a dog
- 17 - has been diagnosed with psychoses, delusions, dementia, active alcohol/substance dependence or moderate to severe TBI
- 18 - has active suicidal, homicidal or cognitive disabilities that would preclude safety of dog and ability to participate
- 19 - has a suicide flag
- 20 - has a social, mental or physical condition that would prevent Veteran for participating in study
- 21 - is participating in another research trial (unless approval is received)
- 22 - has the National CPRS flag for violent/disruptive behavior
- 23 - has children younger than the age of 5 in the household for more than 8 hours per day, one day a week or more.

Form 24 - Study Completion/Termination



DataFax #004

Plate #241

Phase Visit

SITE NO. PARTICIPANT ID ALPHA CODE DATE OF COMPLETION/TERMINATION
 Month Day Year

FORM 24 - Study Completion/Termination

Complete this form for all randomized participants upon completion of, or termination from the study.

1. Select the reason for study termination.

- Completed study
- Participant not able to adequately care for dog
- Participant moving out of area
- Family decision to withdraw
- Termination due to medical reason, Specify: _____

Participant died. Complete Serious Adverse Event Form 27 and record SAE #:

Dog died. Complete Serious Adverse Event Form 27a and record SAE #:

Participant was terminated due to serious adverse event (SAE) other than death.

Form #: SAE#: Form#: SAE#:

Change in eligibility status (select 1 below)

Exclusionary criteria identified during the observational phase (after screening but before clearing). Please specify criteria number(s) the participant did not meet.

Participant did not pass clearing visit inclusion/exclusion criteria (Indicate criteria on FORM 16)

Exclusionary criteria identified after home clearing visit. Please specify criteria number(s) the participant did not meet.

Cannot be located and is considered permanently lost to follow-up

Incarcerated

Form 24 - Study Completion/Termination



DataFax #004

Plate #242

Phase

Visit

SITE NO.

PARTICIPANT ID

ALPHA CODE

Discontinued mental health treatment

Participant was administratively discharged. Specify incident: _____

Other: Specify: _____

2. Was an adverse event (AE) associated with this termination? Yes No

If yes, record Form # and AE#.

Form #:

AE#:

Form#:

AE#:

3. Did the participant withdraw consent/HIPAA Authorization? Yes No

4. If terminated, was the termination based on a voluntary request by the participant? Yes No

Form Completed By: _____ Date: _____

Investigator's Signature: _____ Date: _____

Form 24a - Final Interview - Service Dogs



DataFax #004

Plate #243

Phase Visit

SITE NO. PARTICIPANT ID ALPHA CODE DATE OF COMPLETION/TERMINATION
 Month Day Year

FORM 24a - Final Interview - Service Dogs

Administer this form upon study completion to participants paired with a service dog.

1. Did your service dog help you with any of your PTSD symptoms?..... Yes No

a. If yes, tell me more (what symptoms? How were they before? How are they now?)

2. In what ways did your service dog help you. (Put an X in the appropriate boxes).

	Not at all	A little	A moderate amount	Quite a lot	Very much
a. The dog helps me go out in public	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. The dog helps me by making me feel more secure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. The dog helps me by making me feel more independent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. The dog helps me by calming me when I feel nervous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. The dog helps me by drawing attention away from me when I am with others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. The dog has helped my physical health. If yes, How?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. The dog has helped my social life. If yes, How?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Form 24a - Final Interview - Service Dogs



DataFax #004

Plate #244

Phase

Visit

SITE NO.

PARTICIPANT ID

ALPHA CODE

Not at all A little A moderate amount Quite a lot Very much

h. The dog helps me by doing the service dog commands (block, behind, bring, sweep and lights)

i. The dog helps me by:

j. The dog helps me by:

k. The dog helps me by:

3. How often did you use each of the 5 service dog tasks - block, behind, bring, sweep, lights. (Interviewer: Put an X in the appropriate boxes)

Often Used (daily) Sometimes Used (weekly) Rarely Used (Less than weekly) Never Used

a. BLOCK (dog in front of you)

b. BEHIND (dog behind you)

c. BRING (retrieve an item)

d. SWEEP (check the room or house for people)

e. LIGHTS (turn on a light switch)

4. Were there any other tasks you would have liked your service dog to be trained to do? Yes No

a. If yes, please list the other tasks. _____

Form 24a - Final Interview - Service Dogs



DataFax #004

Plate #245

Phase

Visit

SITE NO.

PARTICIPANT ID

ALPHA CODE

5. Why have you decided to keep/not keep your service dog?

6. What were the most positive things about having a service dog?

See Form 21. Q. 17

7. What were the most negative things about having a service dog?

See Form 21. Q. 18

8. How have other people in your life reacted to your relationship with your service dog?



DataFax #004

Plate #246

Phase

Visit

SITE NO.

PARTICIPANT ID

ALPHA CODE

9. Do you think your family or friends would say the service dog helped you? Yes No

a. If yes, in what ways? _____

10. Do you do any activities now that you did not do before? Yes No

a. If yes, what? **See Form 21. Q. 20** _____

11. Has your daily life changed since you got the dog? Yes No

a. If yes, How? **See Form 21. Q. 16** _____

12. Do you think you have changed since getting your service dog? Yes No

a. If yes, How? _____



DataFax #004

Plate #247

Phase

Visit

SITE NO.

PARTICIPANT ID

ALPHA CODE

13. Since starting the study, have you ever thought life was not worth living?

 Yes No

a. If yes, has your relationship with your service dog influenced those thoughts? How?

14. Do you have any words of advice or suggestions for veterans who might be interested in a service dog to help with PTSD?

15. Have you owned a dog in the past?

 Yes No

a. Did it affect your relationship with your service dog that you received as part of the study?

 Yes No

b. If yes, how?

Form 24a - Final Interview - Service Dogs



DataFax #004

Plate #248

Phase

Visit

SITE NO.

PARTICIPANT ID

ALPHA CODE

16. Which of these was most helpful to you? Second most? Third most? (Interviewer: Enter no. 1, 2, and 3 by appropriate responses)

The dog doing the five service dog commands (block, behind, bring, sweep, and lights)

The fact I could go out in public with my service dog

The emotional bond between me and my service dog

17. Since starting the study have you taken up anything like yoga, acupuncture, or other non-traditional therapies for your PTSD? Yes No

a. If yes, what were these? Have they helped? _____

18. Did you encounter any businesses that refused to allow your service dog on the premises? Yes No

a. If yes, what did you do?

See Form 21. Q. 26 _____

19. Additional comments: _____

Form Completed By: _____ Date: _____

Investigator's Signature: _____ Date: _____

Form 24b - Final Interview - Emotional Support Dogs



DataFax #004

Plate #401

Phase

Visit

SITE NO.

PARTICIPANT ID

ALPHA CODE

DATE OF COMPLETION/TERMINATION

Month

Day

Year

FORM 24b - Final Interview - Emotional Support Dogs

Administer this form upon study completion to participants paired with an emotional support dog.

1. Did your emotional support dog help you with any of your PTSD symptoms? Yes No

a. If yes, tell me more (what symptoms? How were they before? How are they now?)

2. In what ways did your emotional support dog help you? (Interviewer: Put an X in the appropriate boxes)

	Not at all	A little	A moderate amount	Quite a lot	Very much
a. The dog helps me go out in public	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. The dog helps me by making me feel more secure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. The dog helps me by making me feel more independent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. The dog helps me by calming me when I feel nervous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. The dog helps me by drawing attention away from me when I am with others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. The dog has helped my physical health. If yes, How?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Form 24b - Final Interview - Emotional Support Dogs



DataFax #004

Plate #402

Phase

Visit

SITE NO.

PARTICIPANT ID

ALPHA CODE

	Not at all	A little	A moderate amount	Quite a lot	Very much
g. The dog has helped my social life. If yes, How?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. The dog helps me by:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. The dog helps me by:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. The dog helps me by:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. Why have you decided to keep/not keep your emotional support dog?

4. What were the most positive things about having an emotional support dog?

See Form 21. Q. 17

Form 24b - Final Interview - Emotional Support Dogs



DataFax #004

Plate #403

Phase

Visit

SITE NO.

PARTICIPANT ID

ALPHA CODE

5. What were the most negative things about having an emotional support dog?

See Form 21. Q. 18

6. How have other people in your life reacted to your relationship with your emotional support dog?

7. Do you think your family or friends would say the emotional support dog helped you? . . . Yes No

a. If yes, in what ways?

8. Do you do any activities now that you did not do before? Yes No

a. If yes, what? See Form 21. Q. 20



DataFax #004

Plate #404

Phase

Visit

SITE NO.

PARTICIPANT ID

ALPHA CODE

9. Has your daily life changed since you got the emotional support dog? Yes No

a. If yes, How? **See Form 21. Q. 16** _____

10. Do you think you have changed since getting your emotional support dog? Yes No

a. If yes, How? _____

11. Since starting the study, have you ever thought life was not worth living? Yes No

a. If yes, has your relationship with your emotional support dog influenced those thoughts? How? _____

12. Have you ever taken your emotional support dog into pet-friendly businesses? Yes No

a. If yes, was this a problem? What took place? _____

Form 24b - Final Interview - Emotional Support Dogs



DataFax #004

Plate #405

Phase

Visit

SITE NO.

PARTICIPANT ID

ALPHA CODE

13. Have you ever taken your emotional support dog to the VA Hospital? Yes No

a. If yes, was this a problem? What took place?

14. Did you purchase a vest for your emotional support dog? Yes No

a. If yes, why did you decide to do this?

15. Do you think people ever confused your emotional support dog for a service dog? Yes No

16. Did you ever try to pass your emotional support dog off as a service dog so you could enter a business with your dog? Yes No

a. If yes, why did you do this? Tell me more about where you went and what happened.

Form 24b - Final Interview - Emotional Support Dogs



DataFax #004

Plate #407

Phase

Visit

SITE NO.

PARTICIPANT ID

ALPHA CODE

20. Additional comments: _____

Form Completed By: _____ Date: _____

Investigator's Signature: _____ Date: _____



DataFax # 004

Plate # 249

<i>Phase</i>	<i>Visit</i>
<input type="checkbox"/>	<input type="checkbox"/>

<i>Site #</i>	<i>Participant ID</i>	<i>Alpha Code</i>	<i>Date Form Completed</i>		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<i>Month</i>	<i>Day</i>	<i>Year</i>

**Form 24c
Dog Trainer Evaluation**

1. Dog Type: Service Dog Emotional Support Dog
2. To be completed for Service Dogs and Emotional Support Dogs

Task	Performed task with <i>1 command</i>	Completed task with correction <i>2 commands</i>	Completed task with cue <i>3 commands</i>	Completed task with assistance <i>4 commands</i>	Unable to perform task <i>>4 commands</i>
Heel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Down	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stay	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Leave it (food)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. To be completed for Service Dogs only

Task	Performed task with <i>1 command</i>	Completed task with correction <i>2 commands</i>	Completed task with cue <i>3 commands</i>	Completed task with assistance <i>4 commands</i>	Unable to perform task <i>>4 commands</i>
Bring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Block	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Behind	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lights	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sweep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Task Definitions:

Performed task with one command: Task is completed after command is given once.

Completed task with correction: Task is completed after command is given twice with a correction

Completed task with cue: Task is completed after command is given 3 times with a cue

Completed task with assistance: Task is completed after command is given 4 times with physical assist

Unable to perform task: Unable to perform task after 4 attempts

Form Completed By: _____ Date _____

Protocol Deviation Codes

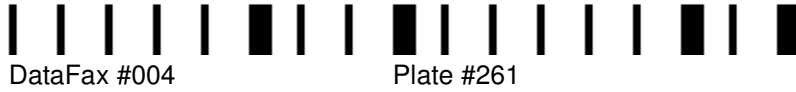
- 01 = Adverse Event not reported
- 02 = SAE not reported
- 03 = SAE reported late
- 04 = Participant not monitored for AE/SAE
- 05 = Did not follow instructions from IRB or other review bodies/committees
- 06 = Confidentiality or privacy breach
- 07 = Loss of source documents/samples/source media
- 08 = Improper enrollment of a member of a vulnerable population
- 09 = Inappropriate participant randomization
- 10 = Ineligible participant enrolled
- 11 = Participant in more than one simultaneous interventional trial
- 12 = Inappropriately modified informed consent/HIPAA
- 13 = Informed Consent/HIPAA documentation completed incorrectly
- 14 = Informed Consent/HIPAA documentation is incomplete
- 15 = Informed Consent/HIPAA not obtained prior to study procedures
- 16 = Reconsent/HIPAA reauthorization not obtained in timely manner
- 17 = Used incorrect informed consent/HIPAA version
- 18 = Intervention used by non-study individual
- 19 = Performed activities not allowed by protocol
- 20 = Performed study procedure at incorrect interval
- 21 = Required study procedure not performed per protocol
- 22 = Study activities performed by inappropriate personnel
- 23 = Study intervention not administered per protocol
- 24 = Participant non-compliance
- 25 = Other (specify under Reason for Deviation)
- 26 = Adverse event for Dog not reported
- 27 = SAE for Dog not reported
- 28 = SAE for Dog reported late
- 29 = Emotional Support Dog seen in public place or VA facility wearing a service dog vest
- 30 = Emotional Support Dog seen in public place or VA facility (no service dog vest)
- 31 = Consented > 74 per site approved by cIRB

FOR SITE USE ONLY. DO NOT SEND TO CSPCC.

Record of Parties Notified (as applicable):

Individual Contacted	Date:	How notified												
a. Chairman's Office	<table><tr><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td></tr><tr><td><i>Month</i></td><td><i>Day</i></td><td colspan="4"><i>Year</i></td></tr></table>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<i>Month</i>	<i>Day</i>	<i>Year</i>				
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b. CSPCC	<table><tr><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td></tr><tr><td><i>Month</i></td><td><i>Day</i></td><td colspan="4"><i>Year</i></td></tr></table>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<i>Month</i>	<i>Day</i>	<i>Year</i>				
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c. cIRB	<table><tr><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td></tr><tr><td><i>Month</i></td><td><i>Day</i></td><td colspan="4"><i>Year</i></td></tr></table>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<i>Month</i>	<i>Day</i>	<i>Year</i>				
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d. RCO	<table><tr><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td></tr><tr><td><i>Month</i></td><td><i>Day</i></td><td colspan="4"><i>Year</i></td></tr></table>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<i>Month</i>	<i>Day</i>	<i>Year</i>				
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<i>Month</i>	<i>Day</i>	<i>Year</i>												
e. Research Office	<table><tr><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td></tr><tr><td><i>Month</i></td><td><i>Day</i></td><td colspan="4"><i>Year</i></td></tr></table>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<i>Month</i>	<i>Day</i>	<i>Year</i>				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>									
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f. Other: _____	<table><tr><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td><td><input type="text"/></td></tr><tr><td><i>Month</i></td><td><i>Day</i></td><td colspan="4"><i>Year</i></td></tr></table>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<i>Month</i>	<i>Day</i>	<i>Year</i>				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>									
<i>Month</i>	<i>Day</i>	<i>Year</i>												

Form 26 - Adverse Events



AE # SITE NO. PARTICIPANT ID ALPHA CODE DATE OF AE REPORT (Month Day Year)

FORM 26 Adverse Event (AE)

Complete this form for each adverse event.

1. Date Adverse Event began: (Month Day Year)

2. When did the AE occur relative to randomization? Pre-randomization Post-randomization

3. Adverse Event (AE) being reported (enter the diagnosis if known; otherwise enter a sign or symptom). If more than 1 adverse event has occurred, report each on a separate form:

4. Outcome (select one):

- Fatal Ongoing - Recovering / Resolving
Recovered / Resolved Recovered / Resolved with Sequelae (no change expected)
Ongoing - Not Recovered / Resolved Unknown

5. If Adverse Event stopped, enter date: (Month Day Year)

6. What is the severity of this AE? Mild Moderate Severe

7. To whom did this AE occur? Participant Family member, or other person in the home

8. Is this AE reasonably attributable to the study intervention (the study dog)?

- Not attributed Possibly attributed Yes, attributed

(Only AEs that are Possibly or Yes, attributed are being collected. If Not attributed, please do not submit this form.)

9. Is the AE attributable to concomitant medications?

- Not attributed Possibly attributed Yes, attributed

10. Is the AE attributable to progression of the disease being studied?

- Not attributed Possibly attributed Yes, attributed

Form 26 - Adverse Events



AE # SITE NO. PARTICIPANT ID ALPHA CODE

11. Is the AE attributable to other patient-related conditions?

Not attributed Possibly attributed Yes, attributed

a. If the AE is attributable or possibly attributed to other patient-related conditions, please specify

12. Did the Adverse Event cause discontinuation from the study? Yes No

13. Is this event serious - Does it meet the definition of a Serious Adverse Event? Yes No

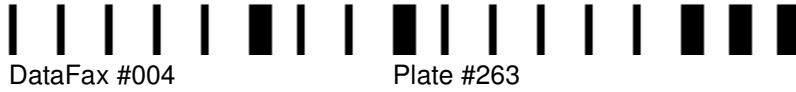
a. If 'Yes', a Serious Adverse Event form (Form 27) must be completed. List SAE #:

14. AE Comments

Form Completed By: Date:

Investigator's Signature: Date:

Form 26a - Adverse Events for DOG



<i>AE NO.</i>	<i>SITE NO.</i>	<i>PARTICIPANT ID</i>	<i>ALPHA CODE</i>	<i>DATE OF AE REPORT</i>		
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
				<i>Month</i>	<i>Day</i>	<i>Year</i>

FORM 26a Adverse Event (AE) for DOG

Complete this form for each adverse event that occurs to the Dog.

1. Date Adverse Event began:

Month Day Year

2. Adverse Event (AE) being reported (enter the diagnosis if known; otherwise enter a sign or symptom). If more than one adverse event has occurred, report each on a separate form: _____

3. Outcome (select one):

- | | |
|---|--|
| <input type="checkbox"/> Fatal | <input type="checkbox"/> Ongoing - Recovering / Resolving |
| <input type="checkbox"/> Recovered / Resolved | <input type="checkbox"/> Recovered / Resolved with Sequelae (no change expected) |
| <input type="checkbox"/> Ongoing - Not Recovered / Resolved | <input type="checkbox"/> Unknown |

4. If Adverse Event stopped, enter date:

Month Day Year

5. What is the severity of this AE? Mild Moderate Severe

The following specific AEs related to the Study Dogs are being collected.

6. Bites of any level, based on the Dunbar dog bite scale:

- a. Level 1 - Obnoxious or aggressive behavior but no skin-contact by teeth. Yes No
- b. Level 2 - Skin-contact by teeth but no skin-puncture. Yes No
- c. Level 3 - One to four punctures from a single bite with no puncture deeper than half the length of the dog's canine teeth Yes No
- d. Level 4 - One to four punctures from a single bite with at least one puncture deeper than half the length of the dog's canine teeth Yes No
- e. Level 5 - Multiple-bite incident with at least two Level 4 bites or multiple-attack incident with at least one Level 4 bite in each Yes No

Form 26a - Adverse Events for Dog

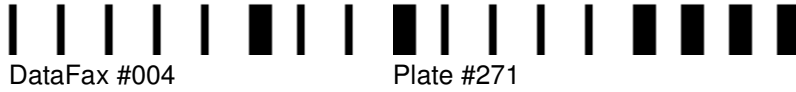
DataFax #004 Plate #264

AE NO. SITE NO. PARTICIPANT ID ALPHA CODE

- f. Level 6 - Death
7. Herding or similar aggressive behavior towards children
8. Diagnosis of any zoonotic parasitic or other disease in the Participant, Participant's family, or in people with regular contact with the dog
9. Unprovoked aggression towards other dogs or cats
10. Aggression of any kind toward people who are exposed to the dog under any environment
11. Repeated refusal of the participant to go to routine veterinary visits, or decisions not to seek veterinary treatment for dog injuries or significant illnesses
12. Diagnosis of chronic illness, hip or elbow dysplasia, or a genetic condition refractory to treatment that will likely reduce the working life of a Service Dog or the ability of an Emotional Support Dog to be a potentially positive factor on the participant
13. Did the Adverse Event cause discontinuation from the study?
14. Is this event serious - Does it meet the definition of a Serious Adverse Event?
a. If 'Yes', a Serious Adverse Event form for the Dog (Form 27a) must be completed. List SAE #:
15. AE Comments

Form Completed By: Date:
Investigator's Signature: Date:

Form 27 - Serious Adverse Events



SAE# [][] SITE NO. [][][] PARTICIPANT ID [][][][] ALPHA CODE [][][][] DATE OF SAE REPORT [][] [][] [][][][]
Month Day Year

FORM 27 Serious Adverse Event (SAE)

Complete this form for each serious adverse event.

1. Date Serious Adverse Event began: [][] [][] [][][][]
Month Day Year

2. When did the SAE occur relative to randomization? [] Pre-randomization [] Post-randomization

3. Brief description of the serious adverse event: _____

4. Serious Adverse Event Type (check ALL that apply):

- [] Death [] Life-threatening
[] Congenital anomaly/birth defect [] Inpatient hospitalization or prolongation of existing hospitalization
[] Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
[] Important medical events that may not result in death, be life threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition

5. If the SAE stopped, enter date: [][] [][] [][][][]
Month Day Year

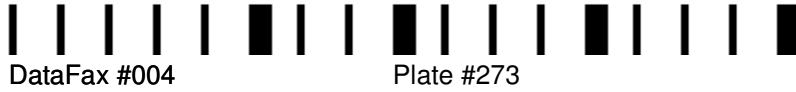
6. If the SAE resulted in death, what is the date of death? [][] [][] [][][][]
Month Day Year

7. Is the date of death an estimate? [] Yes [] No

8. Date the Site Staff became aware of the event: [][] [][] [][][][]
Month Day Year

9. Describe the Serious Adverse Event, including treatment of the event: (Describe patients condition just prior to, during and after event - if known give the duration and outcome of this event - DO NOT include past medical history.)

Form 27 - Serious Adverse Events



SAE#	SITE NO.	PARTICIPANT ID	ALPHA CODE
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

17. Concomitant Medications taken at the time of the SAE onset:

_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

18. SAE Comments: _____

19. Did the Serious Adverse Event cause discontinuation from the study? Yes No

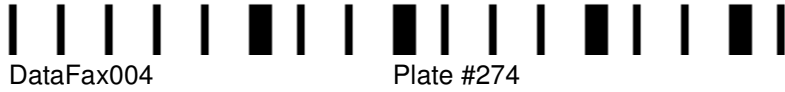
20. Is a SAE follow-up form (Form 28) required? Yes No

A SAE follow-up form is required if the SAE is ongoing-recovering/resolving or ongoing-not recovered/resolved.

Form Completed By: _____ Date: _____

Investigator's Signature: _____ Date: _____

Form 27a - Serious Adverse Events for Dogs



SAE# [][] SITE NO. [][][] PARTICIPANT ID [][][][] ALPHA CODE [][][][] DATE OF SAE REPORT [][][][][]
Month Day Year

FORM 27a Serious Adverse Event (SAE) for Dogs

Complete this form for each serious adverse event in a dog.

1. Date Serious Adverse Event began: [][][][][]
Month Day Year

2. Serious Adverse Event Type (check ALL that apply):

- Death Life-threatening
Congenital anomaly/birth defect Inpatient hospitalization or prolongation of existing hospitalization
Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
Important medical events that may not result in death, be life threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the dog and may require medical or surgical intervention to prevent one of the outcomes listed in this definition

3. If the SAE resulted in dog death, what is the date of death? [][][][][]
Month Day Year

4. Is the date of death an estimate? [] Yes [] No

5. Date the Site Staff became aware of the event: [][][][][]
Month Day Year

6. If SAE stopped, enter Date: [][][][][]
Month Day Year

7. Describe the Serious Adverse Event, including treatment of the event: (Describe dogs condition just prior to, during and after event - if known give the duration and outcome of this event - DO NOT include past medical history.)

Horizontal lines for text entry.

Form 27a- Serious Adverse Events for Dogs



SAE #	SITE NO.	PARTICIPANT ID	ALPHA CODE
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

8. If the SAE involved a dog bite, please indicate the level using the Dunbar Bite Scale:

- a. Level 1 - Obnoxious or aggressive behavior but no skin-contact by teeth Yes No
- b. Level 2 - Skin-contact by teeth but no skin-puncture Yes No
- c. Level 3 - One to four punctures from a single bite with no puncture deeper than half the length of the dog's canine teeth Yes No
- d. Level 4 - One to four punctures from a single bite with at least one puncture deeper than half the length of the dog's canine teeth Yes No
- e. Level 5 - Multiple-bite incident with at least two Level 4 bites or multiple-attack incident with at least one Level 4 bite in each Yes No
- f. Level 6 - Death Yes No

9. Indicate if the SAE involved:

- a. Herding or similar aggressive behavior towards children. Yes No
- b. Diagnosis of any zoonotic parasitic or other disease in the Participant, Participant's family, or in people with regular contact with the dog. Yes No
- c. Unprovoked aggression towards other dogs or cats Yes No
- d. Aggression of any kind toward people who are exposed to the dog under any environment . Yes No
- e. Repeated refusal of the participant to go to routine veterinary visits, or decisions not to seek veterinary treatment for dog injuries or significant illnesses. Yes No
- f. Diagnosis of chronic illness, hip or elbow dysplasia, or a genetic condition refractory to treatment that will likely reduce the working life of a Service Dog or the ability of an Emotional Support Dog to be a potentially positive factor on the participant Yes No

10. Outcome for Dog(select one):

- | | |
|---|--|
| <input type="checkbox"/> Fatal | <input type="checkbox"/> Ongoing - Recovering / Resolving |
| <input type="checkbox"/> Recovered / Resolved | <input type="checkbox"/> Recovered / Resolved with Sequelae (no change expected) |
| <input type="checkbox"/> Ongoing - Not Recovered / Resolved | <input type="checkbox"/> Unknown |

Form 28 - SAE Follow-Up

DataFax #004

Plate #281

SAE #	Follow-up#	SITE #	PARTICIPANT ID	ALPHA CODE	DATE OF SAE FOLLOW-UP		
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <i>Month</i>	<input type="text"/> <i>Day</i>	<input type="text"/> <i>Year</i>

FORM 28 Serious Adverse Event (SAE) Follow-Up

Complete this form every 30 days for each ongoing serious adverse event.

1. Date Serious Adverse Event began:
Month Day Year

2. Date of original SAE Report:
Month Day Year

3. Has the SAE being reported changed from the Initial Serious Adverse Event Report? Yes No
(e.g., event originally reported as chest pain, but final diagnosis is MI.)

a. If 'Yes' indicate the change in the SAE being reported: (Enter only the diagnosis if known; otherwise enter a sign or symptom. Do not enter Death or Hospitalization as an event.)

4. Serious Adverse Event Type (check ALL that apply):

- Death Life-threatening
- Congenital anomaly/birth defect Inpatient hospitalization or prolongation of existing hospitalization
- Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- Important medical events that may not result in death, be life threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition

5. If the SAE resulted in death, what is the date of death?
Month Day Year

6. Is the date of death an estimate? Yes No

7. Is there additional new information to report? Yes No

a. If 'Yes', please specify _____

Form 28 - SAE Follow-Up



DataFax #004

Plate #282

SAE #	Follow-up #	SITE #	PARTICIPANT ID	ALPHA CODE
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

8. Has the ATTRIBUTION of the SAE changed from the initial report? Yes No

a. If 'Yes', is this SAE reasonably attributable to the study intervention (the study drug)?

Not attributed Possibly attributed Yes, attributed

b. Is the SAE attributable to concomitant medications?

Not attributed Possibly attributed Yes, attributed

c. Is the SAE attributable to progression of the disease being studied?

Not attributed Possibly attributed Yes, attributed

9. Outcome (select one):

- Fatal
- Recovered / Resolved
- Ongoing - Not Recovered / Resolved
- Ongoing - Recovering / Resolved
- Recovered / Resolved with Sequelae (no change expected)
- Unknown

10. If Serious Adverse Event stopped, enter date:
Month Day Year

11. Is the SAE Stop Date an estimate? Yes No

12. SAE Comments: _____

13. Is a SAE follow-up form (Form 28) required? Yes No

Another SAE follow-up form is required if the SAE is ongoing-recovering/resolving or ongoing-not recovered/resolved.

Form Completed By: _____ Date: _____

Investigator's Signature: _____ Date: _____

Form 28a - SAE Follow-Up for Dogs

DataFax #004

Plate #283

SAE #	Follow-up#	SITE #	PARTICIPANT ID	ALPHA CODE	DATE OF SAE FOLLOW-UP		
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <i>Month</i>	<input type="text"/> <i>Day</i>	<input type="text"/> <i>Year</i>

FORM 28a Serious Adverse Event (SAE) Follow-Up for Dogs

Complete this form every 30 days for each ongoing serious adverse event in a dog.

1. Date Serious Adverse Event began:
Month Day Year

2. Date of original SAE Report:
Month Day Year

3. Has the SAE being reported changed from the Initial Serious Adverse Event Report? Yes No
(e.g., event originally reported as chest pain, but final diagnosis is MI.)

a. If 'Yes' indicate the change in the SAE being reported: (Enter only the diagnosis if known; otherwise enter a sign or symptom. Do not enter Death or Hospitalization as an event.)

4. Serious Adverse Event Type (check ALL that apply):

- Death Life-threatening
- Congenital anomaly/birth defect Inpatient hospitalization or prolongation of existing hospitalization
- Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- Important medical events that may not result in death, be life threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition

5. If the SAE resulted in death, what is the date of death?
Month Day Year

6. Is the date of death an estimate? Yes No

7. Is there additional new information to report? Yes No

a. If 'Yes', please specify _____

Form 28a - SAE Follow-Up for Dogs

DataFax #004

Plate #284

SAE #	Follow-up #	SITE #.	PARTICIPANT ID	ALPHA CODE
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

8. Outcome (select one):

- Fatal
- Recovered / Resolved
- Ongoing - Not Recovered / Resolved
- Ongoing - Recovering / Resolving
- Recovered / Resolved with Sequelae (no change expected)
- Unknown

9. If Serious Adverse Event stopped, enter date:
Month Day Year

10. Is the SAE Stop Date an estimate? Yes No

11. SAE Comments: _____

12. Is another SAE follow-up form (Form 28a) required? Yes No

Another SAE follow-up form is required if the SAE is ongoing-recovering/resolving or ongoing-not recovered/resolved.

Form Completed By: _____ Date: _____

Investigator's Signature: _____ Date: _____

Form 86 - Informed Consent Confirmation



Consent # [][] SITE # [][][] PARTICIPANT ID [][][][] ALPHA CODE [][][][] DATE OF SUBMISSION [][] [][] [][][][]
Month Day Year

FORM 86 Informed Consent Confirmation

Complete this form after the participant has signed the Informed Consent.

- 1. Participant's social security number [][][] - [][] - [][][][]
- 2. Date consent signed: [][] [][] [][][][]
Month Day Year
- 3. Participant consented by: _____
- 4. Did the participant have a referral letter signed by a treating mental health provider? Yes No
- 5. Date referral letter signed: [][] [][] [][][][]
Month Day Year
- 6. Name of treating mental health provider: _____
- 7. Address of treating mental health provider: _____

- 8. Phone Number of treating mental health provider:
[][][] - [][][] - [][][][] Ext. [][][][][][]
- 9. After hours phone number of treating mental health provider:
[][][] - [][][] - [][][][] Ext. [][][][][][]
- 10. E-mail address of treating mental health provider: _____
- 11. Participants Initials: [][][]

Form Completed By: _____ Date: _____

Investigator's Signature: _____ Date: _____