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Assessing Behavioral Engagement in Clinical Research: The Wintering Donnelly Research Assessment & Screening Tool (WRAST)

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Assessing Behavioral Engagement in Clinical Research: The Wintering Donnelly Research Assessment and Screening Tool (WRAST)

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Abstract: The content for this paper was presented originally by the first author at the 2017 SOCRA Annual Conference in a talk entitled, "Assessing Behavioral Engagement in Clinical Research." We introduce the Wintering Donnelly Research Assessment Screening Tool (WDRAST). The WDRAST can be used as an adaptable screening and assessment tool in clinical research. By taking a proactive approach, research personnel can identify, prepare, and plan for the needs of individual research participants or particular patient populations. The WDRAST can be used to evaluate research participants' psychological, physiological, cognitive, social, and functional strengths and needs. With planning, the WRAST can identify the needs of individuals or patient populations to ensure greater success in engagement, project planning, protocol adherence, and study retention.

Overview

By adapting approaches from behavioral health treatment to a clinical research setting, the WDRAST can assess and identify each participant's particular needs. Research personnel are presented with study populations who exhibit a wide variety of behaviors. The WDRAST can help researchers to prepare for specific patient population needs in order to ensure greater success in engagement, project planning, and retention.

With a more in-depth understanding of research participants needs, we can plan accordingly to address their concerns while forging an effective partnership between researchers, participants, and their families. To understand behavioral assessment, it is important to define some key terms and concepts: screening, assessment,

needs assessment, communication, engagement, behavior management, and biopsychosocial model.

Screening

The purpose of screening is to evaluate the presence or absence of a problem, condition, or need. Usually, the answer is a "yes" or "no."

Assessment

Assessment is a process used to gather information to determine the extent and duration for defining a problem, making a diagnosis, and developing recommendations for addressing a problem, diagnosis, or need.

Needs Assessment

A needs assessment is a process to identify and address specific needs or wants in order to move toward a more desirable state of being with adequate supports and services. The results from this assessment can be used to plan in advance what the specific study population may need. It can also identify reasonable expectations that are also flexible.

Communication

To communicate with study participants effectively, it is important to clearly explain the study procedures and what is expected to occur. It is important to be able to evaluate the subject's capacity for understanding and concentration.

Engagement

Engagement is a process that involves and empowers participants in their support system to be involved. To have a subject be engaged in a study, it is important to understand the subject's motivation and interest. In a research

TABLE 1

Behavior Management Strategies

- Assess the situation and condition
- Prepare for unique needs of the study population
- Utilize tools or sources to gather information
- Brief staff and key personnel
- Plan an approach that addresses and meets the needs of the participant and the study
- Huddle to discuss challenges and systematic barriers as they arise
- Debrief: what have you learned from the encounter?

study, each participant may experience his or her disease or condition differently. Engagement can be achieved by creating a patient-centered environment that is adaptable to each subject's needs. The WDRAST can be used as a comprehensive tool that describes each person's capacities and needs in order to enable the study staff to prepare for accommodations that may be needed to promote strategies that are responsive to participant needs.

Behavior Management Approach

There is an educational component to the interactions with research participants. Positive interactions can be reinforced or rewarded. Behaviors that work against achieving the research objectives can be discussed and reframed with the participant by explaining and modeling the expected behaviors. However, assessing the capacity to understand the process is important for participants and research staff.

It is important to recognize how behavior and attitude affects you and the people around you and to be aware of how your reactions to a participant or their situation affects the interpersonal dynamics of others. Talk to a person with a condition as a person, not as a diagnosis. Responses can exacerbate or de-escalate a situation. Recognize the impact of your social role, particularly if you come from a different social or cultural background than the participant.

Biopsychosocial Model

As a screening and assessment tool, the WDRAST is based upon a biopsychosocial model that considers the biological, psychological, and sociological factors that can be attributed to disease outcomes. Biological factors include symptoms, disease, disorders, or genetics. Psychological factors include mood, personality, and behavior. Social factors can include cultural, familial, and socioeconomical.

The development of the biopsychosocial model was originally published in 1977 by psychiatrist George L. Engel, who revolutionized the existing medical model. Before Engel, disease was based solely on presentation of symptoms; diagnosis was followed by a standardized intervention or treatment. However, an individual's response to a disease based upon their individual characteristics was not considered. Engel's model is based on a social cognitive theory based on the notion that treatment requires the health management team to address more than the symptoms; they must address the disease-causing factors. It is important to evaluate the social, biological, and psychological influences on a patient's treatment. The biopsychosocial model looks at how attributes and perception of disease can affect the outcome.

Social Cognitive Theory suggests that human behavior is caused by personal, behavioral, and environmental influences. The concepts of holistic or patient-centered approaches recognize that the mind can influence the body just as the body can influence the mind.

In contemporary society, we may take it for granted that attitudes, perspectives, and social supports can have an impact on a patient's treatment response and view of their condition. Historically, the biopsychosocial model has been used for approximately fifty years.

The benefits of using a biopsychosocial approach in research planning are that it enables the study staff to plan in advance and to formulate reasonable expectations for individuals and study populations. It also is a method to anticipate and meet participants' specific needs. The WDRAST uses a biopsychosocial approach in order to gather information to share with members of the interdisciplinary team and to promote more effective care.

How to Use the Wintering Donnelly Research Assessment and Screening Tool

The WDRAST identifies needed supports and accommodations, and it includes a message log and five content areas: demographics, social and cultural, physical health, psychological health, and functional capacity.

Supports and Accommodations

After the completing the form, the interviewer will write a brief

summary in the comment sections and then record areas of support and accommodations that need to be made in order for the participant to have successful participation. This format is a quick way to view the need for different accommodations to be made rather than searching through the entire form.

Message Log

The first section is used to maintain records of all those who have obtained information from the subject on the WDRAST. The date, method of assessment, and contact note are recorded and initialed. The form can be completed through a chart abstraction, a phone interview, or an in-person interview with the participant and/or caregiver.

Demographics

The demographics section includes name, age, date of birth, gender, ethnicity, height and weight, and contact/communication information. This section will determine the primary method of contact for the participant for the duration of the study. This is also an area to identify whether one has a Legally-authorized Representative (LAR) or proxy who will be involved during the study.

Social and Cultural

Social Support evaluations are important to determine an individual's capacity for self-management. Areas of evaluation can include types of social support, impact on family and caregivers, how adaptable the family and individual are, and any specific cultural and social considerations. This section identifies preferences for language and cultural considerations. It also identifies factors that could

affect communication, education, and potential conflicts of commitment and scheduling that could arise in the duration of the study. When this section is completed, it can assist staff to prepare for whether subjects need a translator or need to have documents translated to ensure that participants have been fully-informed about the study. This section can also gather information needed to plan the scheduling of appointments around the participants work schedule or other responsibilities. Research staff can be alerted to whether the participant may move or have a change in living situation during the study, and they can identify transportation needs or barriers to maintaining study appointments.

Physiological Health: Physical Health and Functional Capacity

This section of the form obtains a brief overview of past and current medical history and any immediate concerns. It can be used to determine how the participant's condition is affecting their physical health. It identifies medical conditions for which the participant is being treated, and whether there are any surgeries or other planned events in the near future that could delay their treatments. This section identifies participant's ambulatory limitations, need for accommodations, and fall risks, in order to plan for patient flow and safe navigation and transport throughout the study.

Psychological Functioning

This section of the WDRAST is used to focus on the participant's mental health needs. It can be used to identify current and past psychological and psychiatric conditions and also to address fears or concerns that the participant may have about study procedures. It can also

identify other psychological stressors and past and/or present brain injuries that may interfere with the participant's overall mental capacity and cognitive functioning. During the interview process, the interviewers should check for learning with the interviewee, especially if the participant does not seem to be attentive.

Suggestions for Administering the WDRAST:

- Become familiar with the form and the biopsychosocial framework
- Schedule an adequate amount of time for the screening process
- Practice administering the WDRAST with peers or colleagues before administering it to a subject
- Adapt the language of the form to the interview based upon who is completing the form
- Ask open-ended questions
- Plan debriefing meetings with research colleagues to review completed forms for planning purposes
- Maintain a copy of the completed form for source documentation
- Begin to arrange accommodations and supports based upon information obtained in the WDRAST

Wintering / Donnelly Research Assessment Screening Tool

Case Example 1

Ms. Sarah James is a 62-year old Caucasian female currently suffering from macular degeneration. She has complete visual impairment and insomnia. She will be coming in for a screening visit due to interest in participating in an insomnia clinical study. Ms. James originally worked as a first grade teacher, but due to her new visual impairment, she has left on disability. Ms. James relies solely on her husband, Ronald James, to bring her to and from appointments and to assist her while she adapts to using a white cane when walking. Ms. James is excellent at following verbal instructions, but she will need them written down for her husband.

	WINTERING BON	NELLY RESEARC	H ASSESSMENT S	CREENING	TOOL			
Supports and A	ccommodations: I	ndicate if addition	al support or cons	ideration is	needed	d in these areas.		
Social YES NO	Physiological ☑ YES □ NO							
Method of Assessmen	nt: □ Phone 🗵 In	Person □ Self-Adn	ninistered 🗵 With fa	mily member	□ Char	t Abstraction		
Internieros lensie	l	MESSA	GE LOG					
Interviewer: Jamie Date:	1				Initials	or Nama of		
Date.	Contact:	Contact: Initials or Name of Person(s) Conducting Screening:						
08/31/2017	Met in Dr. Henr	Met in Dr. Henry's office JL						
08/31/2017		d) came to read and v	vrite for subject		JL			
Comments: Subject		asian female suffering		eration. She l	nas com	plete visual		
		ating in an insomnia c						
Physiological: Blind	ness and problems wi	ith sleeping; uses a wl	nite cane when walkir	ng				
Communication: Ca	n follow verbal instru	ıctions						
Accommodations: Unable to drive; needs instructions to be verbal or written down for her husband								
Case Example 2 Mr. John Smith is	a 33-year old Africar	n American male rece	ntly diagnosed with M	Iultiple Sclero	osis (MS			
Case Example 2 Mr. John Smith is because he wishes wife, Emma Smitl	a 33-year old Africans to be involved in a can. Mr. Smith coaches but he is on no other		ntly diagnosed with M will be coming in fo e and has children at h	Iultiple Scleror a screening vis home. Mr.	osis (MS visit acc Smith ta	ompanied by his akes oxycodone		
Case Example 2 Mr. John Smith is because he wishes wife, Emma Smith for pain as needed	a 33-year old Africar to be involved in a c n. Mr. Smith coaches l, but he is on no other MS.	n American male receilinical trial. Mr. Smith	ntly diagnosed with Maxwell be coming in fore and has children at he recently has been ha	fultiple Sclero r a screening his home. Mr. aving increase	osis (MS visit acco Smith to ed anxiet	ompanied by his akes oxycodone		
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Case Example 2 Mr. John Smith is because he wishes wife, Emma Smith for pain as needed issues due to his M Supports and A Social YES □ NO	a 33-year old Africar to be involved in a can. Mr. Smith coaches but he is on no other MS. WINTERING DON ccommodations: I Physiological YES □ NO	American male receilinical trial. Mr. Smith youth soccer part-time daily medications. His section of the sectio	ntly diagnosed with Maxwill be coming in fore and has children at he recently has been had a support or consumption of the communication of the communicatio	Tultiple Scleror a screening vis home. Mr. aving increase CREENING ideration is Support □ YES	osis (MS visit access Smith taked anxiet TOOL needed	d in these areas. Accommodations YES □ NO		
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Case Example 2 Mr. John Smith is because he wishes wife, Emma Smith for pain as needed issues due to his M Supports and A Social YES NO Method of Assessment	a 33-year old Africar to be involved in a c.n. Mr. Smith coaches but he is on no other MS. WINTERING DON ccommodations: I Physiological YES □ NO nt: □ Phone ☑ In	American male receilinical trial. Mr. Smith youth soccer part-time daily medications. His section of the sectio	ntly diagnosed with Maxwill be coming in force and has children at he recently has been had a support or consideration YES NO NO Ininistered With fa	fultiple Scleror a screening wis home. Mr. aving increase CREENING ideration is Support YES mily member	osis (MS visit acco Smith ta ed anxiet TOOL needec	ompanied by his akes oxycodone by and memory d in these areas. Accommodations YES □ NO		
Case Example 2 Mr. John Smith is because he wishes wife, Emma Smith for pain as needed issues due to his M Supports and A Social YES □ NO	a 33-year old Africar to be involved in a c.n. Mr. Smith coaches but he is on no other MS. WINTERING DON ccommodations: I Physiological YES □ NO nt: □ Phone ☑ In	American male receilinical trial. Mr. Smith youth soccer part-time daily medications. His section of the sectio	ntly diagnosed with Maxwill be coming in force and has children at he recently has been had a support or consideration YES NO NO Ininistered With fa	fultiple Scleror a screening wis home. Mr. aving increase CREENING ideration is Support YES mily member	osis (MS visit acco Smith ta ed anxiet TOOL needec	ompanied by his akes oxycodone by and memory d in these areas. Accommodations YES □ NO		

Wintering / Donnelly Research Assessment Screening Tool, Cont'd. Screening: 08/30/2017 Subject completed form with wife (Emma) in Dr. Patterson's office Comments: The subject is a 33-year old African American male with recent diagnosis of Multiple Sclerosis. He is interested in a new experimental Multiple Sclerosis clinical trial. Physiological: Multiple Sclerosis and pain due to Multiple Sclerosis Psychological: Anxiety and Memory due to early symptoms of Multiple Sclerosis Case Example 3: Mr. Kevin Kim is an 88-year old non-English speaking Korean male with progressive cognitive impairment. He will be accompanied by his son, Jake Kim, to his appointments to provide translation. Jake is also Mr. Kim's legally authorized representative due to his father's increase in cognitive impairment. If Jake is unavailable to attend an appointment, a Korean translator will be needed. Aside from cognitive impairment, Mr. Kim also is on medication for hypertension and hyperlipidemia. Mr. Kim also is hard of hearing, wears glasses, and ambulates slowly with assistance from a cane. WINTERING DONNELLY RESEARCH ASSESSMENT SCREENING TOOL Supports and Accommodations: Indicate if additional support or consideration is needed in these areas. Social Physiological Psychological Communication Support Accommodations ☐ YES ☐ NO ☐ YES ☐ NO ▼ YES □ NO YES □ NO ▼ YES □ NO ☑ In Person □ Self-Administered ☑ With family member □ Chart Abstraction Method of Assessment: ☐ Phone **MESSAGE LOG** Interviewer: Chris Doe **Method of Assessment:** □ Phone ☑ In Person ☐ Self-Administered ☑ With family member ☐ Chart Abstraction Date: Contact: **Initials or Name of** Person(s) Conducting Screening: 08/31/2017 Met in Dr. Jones's clinic with patient CD 08/31/2017 Interview conducted with adult son (Jake); Patient was present CD Comments: Subject moves slowly, widowed elder, Korean male with mild cognitive impairment; provide written instructions for son; the subject is currently being treated for hypertension and hyperlipidemia Social: Subject had limited understanding of English language; son can translate Physiological: hypertension, hyperlipidemia, wears glasses, hard of hearing; past smoker

Psychological: Memory problems

Accommodations: Language, walking slowly with cane Communication: Needs translator if son is not present

Wintering / Donnelly Research Assessment Screening Tool, Cont'd.

Case Example 4

Ms. Jennifer Jacobs is a 43-year old Caucasian female presenting for a screening visit for a new breast cancer study due to a recent breast cancer diagnosis. Ms. Jacobs recently lost her husband and is now working full-time as a NICU nurse to provide for her three young children. Ms. Jacobs needs to schedule research appointments around her work, although she is planning to apply for disability and find childcare arrangements. Ms. Jacobs has a penicillin allergy and no other significant past medical history. She now is experiencing mild pain due to her cancer, as well as stress, anxiety, and depression due to the loss of her husband and her recent cancer diagnosis.

WINTERING DONNELLY RESEARCH ASSESSMENT SCREENING TOOL								
Supports and Accommodations: Indicate if additional support or consideration is needed in these areas.								
Social ■ YES □ NO	Physiological ■ YES □ NO	Psychological ☑ YES □ NO	Communication ☐ YES ☐ NO	Support X YES	□ NO	Accommodations ■ YES □ NO		
Method of Assessment: ☐ Phone ☑ In Person ☐ Self-Administered ☑ With family member ☐ Chart Abstraction								
MESSAGE LOG								
	0/84 !!	IVILSSA	<u> </u>					
Interviewer: Megan	O'Malley							
Method of Assessm Abstraction	ent: □ Phone 🗷	In Person □ Self	f-Administered	With family r	nember	r □ Chart		
Date:	Contact:				Initials or Name of			
						n(s) Conducting		
08/31/2017	Name: In person, in Dr	Smith's Office	Location:		Screen MO	ing:		
		d, middle-aged, caucas						
determining whether to enroll in a breast cancer trial or follow a traditional treatment plan. Physiological: Breast Cancer, Penicillin allergy, and some pain due to Breast CA Psychological: Anxiety, Depression, Stress, recent loss of husband, three young children to provide for, recent cancer diagnosis Accommodations: Scheduling appointments while children are in school and around work schedule								
DEMOGRAPHICS								
Name: First: Jeni	nifer (JJ for short)	Middle	:	Last: Jacob	os			
Address: 123 Apple Butter Rd. Philadelphia, PA 19104								
Date of Birth: 05/01/1974 Age: 43 (at interview)			Ethnicity: Caucasian					
Gender: □ Male	. ⊠ Fem	Height: 5'6"	W	Weight: 130lbs				
If female: Of childle	pearing potential?	ĭ YES □ NO Preg	nant? □ YES 🗷 N	O Breastfee	eding?] YES ⊠ NO		
Cell Phone: 123-	-456-7890		Home Phone: 098-765-4321					
E-Mail Address: jj45@gmail.com								

V	Vintering / Doni	nelly Resear	ch Assessment Scr	eening Tool, Cont'o	i.	
Preferred method of	of communication	n: ⊠ Phone	(Cell) □ Mail □	Email With famil	y member	
Do subject have a I ☐ YES ☑ NO	egally authorize	d representa	ative or proxy who v	ill provide informed	d consent?	
SOCIAL AND CULT	URAL					
Primary Language spoken by subject: English				Do you need speaking?	a translator for	
	ral consideratio If yes, please e		enhance or otherwi	e effect your resea	rch participation?	
	ed 🗷 Full time 🗆		Retired Unemploy	ed Other:		
Highest level of Ed Do you have other ☑ Childcare ☐ Eld Will someone be as	commitments the dercare ☐ Care	nat could affe egiver 坚 T	ect your participatio ransportation for othe ments?			
☐ YES ☑ NO	oroblems with transfer of Yes, Please	ansportation se explain:	to attend your rese			
□ YES ⊠ NO			tuation, residence o	do you have trave	I plans?	
CONTACT INFORM	ATION					
Primary emergency First: Scott Last: Jefferson Relationship: brothe		and relations	ship:	Phone: Home: 753-4 Cell: 135-790 Email: sxj42)-2468	
PHYSIOLOGICAL H	IFALTIL DUVOL	CAL LIEALTI				
Do you have any ki ☑ YES □ NO List: Penicillin			How is your appet ☐ Good ☒ Fair Comment:	te?		
Do you have any vision problems? ☐ YES ☑ NO		⊠ NO	Do you have any problems with hearing? ☐ YES ☑ NO	Do you have any v ☐ YES ☑ NO	vision problems?	
On average, how m			get per night? <u> 4</u> ney affect your		oct vour energy	
sleeping? ☐ YES ☑ N	sleeping? concentrati			If yes, do they affect your energy level? ☐ YES ☑ NO		
Are you currently b ☑ YES ☐ NO	eing treated for Anxiety-Xanax	any medical Depression	■ NO I condition? If Yes, In-Effexor Breast Ca	lease explain.	NO.	
Do you have any po	•	s?⊔ YES	⊠ NO			

Wintering / Donnelly Research Assessment Screening Tool, Cont'd.

PHYSIOLOGICAL HEALTH: PHYSICAL HEALTH (continued)						
Do you have any of the following conditions? Do you have pain?						
⊠ Cancer		ld breast tenderness				
□Cardiac	□ NO ·					
□Diabetes	On average, rate ye	our pain on a scale of 1-10 (10 being				
□Gastrointestinal	the worst).					
□Genetic						
□Lung/Pulmonary	4					
□Musculoskeletal						
□Neurodegenerative	Are you taking any	thing for pain?				
□Urinary Frequency	☐ YES ☑ NO					
□Other:	List:					
□None						
Have you ever had a head injury or	If yes, did you have	e loss of consciousness?				
concussion?	☐ YES ☑ NO	c loss of consciousness:				
□ YES	IF yes, how long?					
⊠ NO	ii yes, new long.					
If yes, please explain:						
Any problems with balance?		Are you able to walk independently?				
☐ YES- Explain:		✓ YES				
▼ NO		□ NO- Explain:				
Any Risk of falling?		Any recent falls?				
If yes, how many falls?		☐ YES				
☐ YES-Explain:		⊠ NO				
ĭ NO		Dates:				
Do you have shortness of breath after walking?	? For example:	Do you use or need any of the				
Walking down a long hallway	•	following?				
☐ YEŠ ☒ NO		□ Cane				
		☐ Crutches				
Have you ever smoked? ☐ YES ☑ NO		☐ Walker				
If yes, answer the following.	☐ Wheelchair					
	☐ PIC line					
☐ Current	□ Oxygen Tank					
□ Past	☐ Other:					
Packs per day:	■ None					
PSYCHOLOGICAL FUNCTIONING						
Do you have any problems with:						
☐ Receiving shots/needles ☐ Blood draws ☐ Claustrophobia ☒ None						
Do you currently have any major life stressors? ■ YES □ NO If Yes, please explain: Recently loss of husband, three young children at home, works full-time to provide for						
	three young children	at nome, works full-time to provide for				
family, recent breast cancer diagnosis						

	Wintering / Don	nelly Res	earch As	ssessment Scree	ning Tool, C	ont'd.		
Have you had any problems with the following? Please select all that apply. If none or not applicable, select none. Thank You (Complete the Supports and A			Currently Experiencing: ☐ Memory Loss ☑ Anxiety ☑ Depression ☐ Alcohol Abuse ☐ Substance Abuse ☐ Post-Traumatic Stress Disorder ☑ Other: Stress ☐ None		☐ Memo ☐ Anxie ☐ Depre ☐ Alcoh ☐ Substar ☐ Post-1 ☐ Other ☑ None			
Thank Tou (Con	ipiete tile oupport	is and Acc	Johnnous	ations Section and	Comments	Above	·)	
				H ASSESSMENT S				
Supports and A	ccommodations: I			al support or cons	ideration is	neede	d in these areas.	
Social ☐ YES ☐ NO	Physiological ☐ YES ☐ NO	Psycholo		Communication ☐ YES ☐ NO	Support □ YES □	⊐ NO	Accommodations ☐ YES ☐ NO	
Method of Assessmen				inistered □ With fa	mily member	□ Char	I t Abstraction	
			MESSA	GE LOG				
Interviewer:								
Method of Assessm Abstraction	ent: □ Phone □	In Persor	n □ Sel	f-Administered □	With family r	nembei	r □ Chart	
Date:	Contact:						or Name of	
	Name:			Location:		Persor Screen	n(s) Conducting	
Comments:								
DEMOGRAPHICS	S							
Name: (First)		(Mi	ddle)		(Last)			
,		,	,		, ,			
Address:								
Date of Birth:		Age: (at interview	')	Ethnicity:				
Gender: □ Male	e □ Fem	ale		Height:	Weig	ht:		

Wintering / Donnelly Research Assessment Screening Tool, Cont'd. If female: Of childbearing potential? ☐ YES ☐ NO Pregnant? ☐ YES ☐ NO Breastfeeding? ☐ YES ☐ NO Cell Phone: **Home Phone:** E-Mail Address: Preferred method of communication: ☐ Phone □ Mail ☐ Email ☐ With family member Does the subject have a legally authorized representative or proxy who will provide informed consent? □ YES SOCIAL AND CULTURAL Primary Language spoken by subject: Do you need a translator for speaking? ☐ YES Are there any cultural considerations that may enhance or otherwise effect your research participation? □ NO If yes, please explain: ☐ YES Occupation: □ Currently employed □ Full time □ Part time □ Retired □ Unemployed □ Other: Highest level of Education completed: Do you have other commitments that could affect your participation in the study? ☐ Childcare ☐ Eldercare ☐ Caregiver ☐ Transportation for others Will someone be assisting you to your appointments? If Yes, Please explain: Do you anticipate problems with transportation to attend your research appointments? ☐ YES If Yes. Please explain: Do you anticipate any changes in your living situation, residence or do you have travel plans? ☐ YES If Yes, Please explain: CONTACT INFORMATION Primary emergency contact name and relationship: Phone: Home: First: Last: Cell: Relationship: Email: PHYSIOLOGICAL HEALTH: PHYSICAL HEALTH AND FUNCTIONAL CAPACITY Do you have any known drug allergies? How is your appetite? ☐ YES ☐ Good ☐ Fair ☐ Poor List: Comments: Do you have any Do you need a hearing aid? Do vou have anv Do you wear glasses? vision problems? problems with ☐ YES ☐ YES ☐ YES hearing? ☐ YES ☐ NO

On average, how many hours of sleep do you get per night?

Wintering / Donnelly Research Assessment Screening Tool, Cont'd. If yes, do they affect your Do you have any problems If yes, do they affect your energy sleeping? concentration? level? ☐ YES ☐ YES ☐ YES Are you currently being treated for any medical condition? If Yes, Please explain. ☐ YES **Do you have any pending surgeries?** ☐ YES If yes, please explain. PHYSIOLOGICAL HEALTH: PHYSICAL HEALTH AND FUNCTIONAL CAPACITY (continued) Do you have any of the following conditions? Do you have pain? □ Cancer ☐ YES-Explain: □Cardiac □Diabetes On average, rate your pain on a scale of 1-10 (10 being □Gastrointestinal the worst). □Genetic □Lung/Pulmonary □Musculoskeletal Are you taking anything for pain? ☐ YES □Neurodegenerative □Urinary Frequency List: □Other: □None If yes, did you have loss of consciousness? Have you ever had a head injury or concussion? ☐ YES ☐ YES IF yes, how long? □ NO If yes, please explain: Any problems with balance? Are you able to walk independently? ☐ YES-Explain: □ YES □ NO □ NO-Explain: Any Risk of falling? Any recent falls? If yes, how many falls have you had? ☐ YES ☐ YES Dates: Do you have shortness of breath after walking? For example: Do you use or need any of the following of these? Walking down a long hallway ☐ YES ☐ NO ☐ Cane ☐ Crutches Have you ever smoked? ☐ YES □ Walker ☐ Wheelchair If yes, answer the following. □ PIC line ☐ Current □ Oxygen Tank ☐ Past ☐ Other: □ None Packs per day: **PSYCHOLOGICAL FUNCTIONING** Do you have any problems with: ☐ Receiving shots/needles ☐ Blood draws ☐ Claustrophobia ☐ None

Wintering / Donnelly Research Assessment Screening Tool, Cont'd. Do you currently have any major life stressors? ☐ YES If Yes, Please explain: Have you had any problems with the **Currently Experiencing:** Past: following? Please select all that apply. ☐ Memory Loss ☐ Memory Loss If none or not applicable, select none. ☐ Anxiety ☐ Anxiety ☐ Depression ☐ Depression ☐ Alcohol Abuse ☐ Alcohol Abuse ☐ Substance Abuse ☐ Substance Abuse ☐ Post-Traumatic Stress Disorder ☐ Post-Traumatic Stress Disorder ☐ Other: ☐ Other: ☐ None ☐ None Thank You (Complete the Supports and Accommodations Section and Comments Above) Conclusion of studies, medical conditions and of care and support for research The WDRAST provides a treatments, clinical populations, and participants that will make their comprehensive review of health clinical settings. This form serves as experience more effective. conditions, but also provides a way to make clinical research more personalized and patient-centered as other sociological, cultural, and psychological factors that may affect well as to improve communication a subject's participation in a study. between the subject and the research This form can be adapted in various team. It allows staff to be prepared, ways to be used with a multitude which results in improved quality References Alsumidaie, Moe. "The Science of Engagement in Clinical Trial Subject Enrollment." Applied Clinical Trials Home, 13 Nov. 2014, www.appliedclinicaltrialsonline.com/science-engagement-clinical-trial-subject-enrollment. 2. Behavior Management." Wikipedia, Wikimedia Foundation, 10 Apr. 2018, en.wikipedia.org/wiki/Behavior management. 3. Center for Substance Abuse Treatment. Substance Abuse Treatment: Addressing the Specific Needs of Women. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2009. (Treatment Improvement Protocol (TIP) Series, No. 51.) Chapter 4: Screening and Assessment. Available from: https://www. ncbi.nlm.nih.gov/books/NBK83253/ 4. Crisis Prevention Institute. "Behavior Management Techniques and Strategies." Crisis Prevention Institute (CPI),

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