

Attachment 7— IDEAL Screening Exam

When the responsibility for administering the IDEAL screening exam transitioned from Westat to the NIA, the NIA exam protocol was not changed significantly. The only exception is that because the exam now takes place at the NIA's BLSA Clinic facility at MedStar Harbor Hospital, it is possible for the blood specimen to be processed and the results delivered in real time. Additionally, if needed for determination of eligibility, an echocardiogram can be administered to consenting screening participants.

The NIA conducts the screening exam in the same manner as it was conducted in the home, but uses their standard BLSA screening exam forms. For the physical exam components, the manner in which the results are recorded differ from the Westat forms. For example, whereas the Westat form includes individual fields for recording a filament test, and Romberg and Pronator Drift tests, the BLSA form, has a single field for recording a CNS/Neurological Exam result. The instruments for the cognitive components, the Blessed Mental Status and the Mini Mental Exam, are the same. The clinic-based screening exam takes approximately two hours.

IDEAL – Screening Examination

OMB No.: 0925-0631
Expiration Date: xx/xx/20xx

Collection of this information is authorized by Public Law 93-296. Rights of study participants are protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the study at any time. Refusal to participate will not affect your benefits in any way. The information collected in this study will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the study. Information provided will be combined for all study participants and reported as summaries. You are being examined in person to complete this instrument so that we can determine your eligibility for IDEAL.

Public reporting burden for this collection of information is estimated to average 120 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0631). Do not return the completed form to this address.

BLSA ID

□ □ □ □

Visit No.

□ 0

BLSA - Screening for eligibility criteria - Level 2 (Visit examination)

[Large empty box for notes]

Tester ID

□ □ □

Date Completed

□ □ / □ □ / 2 0 □ □

Height

□ □ □ . □ cm

Weight

□ □ □ . □ kg

Age:

□ □ □ years

BMI _____ . _____ (m²/kg)

Medical Record #

0 0 0 □ □ □ □ □ □ □ □

Gender: M F

Race: W B Native Asian Other Mixed Refused

English Primary Language? Y N

Consent for Protocol/ HIPAA/ HIV consent obtained? Y N

Allergies: Y N

[Large empty box for allergies]

Medications:

No Medications

[Large empty box for listing medications]

Do any of these medications make the screenee ineligible for BLSA participation? Y N

Chair Stands

Enter time for 5 stands

□ □ . □ □
Seconds Hundredths

Vital Signs:

Time: □ □ : □ □ T □ □ □ □ °F □ □ Tymp Oral P □ □ □ □ R □ □ B/P S □ □ □ □ D □ □ □ □ arm L R

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BLSA ID
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Visit No.
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**BLSA - Screening for eligibility criteria
- Level 2 (Visit examination)**

Tester ID
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Eligibility Criteria: Response to the following (except Apheresis) must be NO

- Unable to perform ADLs without assistance? _____ 0 = No 1 = Yes
- Unable to perform IADLs without assistance? _____ 0 = No 1 = Yes
- Unable to walk **independently** at least 400 meters? _____ 0 = No 1 = Yes
- Shortness of Breath with ADL or walking 2 flights of stairs? _____ 0 = No 1 = Yes
- Substantial Cognitive impairment (MMSE \leq 24 or Blessed \geq 4) _____ 0 = No 1 = Yes
- History of Cardiovascular Disease? (except controlled HTN) _____ 0 = No 1 = Yes
- History of Cardiovascular Surgery or Intervention? _____ 0 = No 1 = Yes
- History of Diabetes? _____ 0 = No 1 = Yes
- History of Cancer within the last 10 years? _____ 0 = No 1 = Yes
• (except locally limited basal cell cancer)
- History of Metabolic Disease? (except controlled hypothyroidism) _____ 0 = No 1 = Yes
- History of severe hormonal dysfunction? (requiring drug treatment) _____ 0 = No 1 = Yes
- History of Neurological diseases? _____ 0 = No 1 = Yes
- History of Birth Defects? (other than minor anatomical abnormalities) _____ 0 = No 1 = Yes
- History of COPD? _____ 0 = No 1 = Yes
- History of CVA? _____ 0 = No 1 = Yes
- History of Genetic Diseases? _____ 0 = No 1 = Yes
- History of Kidney Disease? _____ 0 = No 1 = Yes
- History of Liver Disease? _____ 0 = No 1 = Yes
- History of severe Gastrointestinal Disease? _____ 0 = No 1 = Yes
- History of Infectious (HIV, HEP B/C)? _____ 0 = No 1 = Yes
- History of Musculoskeletal conditions due to disease or trauma? _____ 0 = No 1 = Yes
- History of Chronic Pain? (use of daily pain medication) _____ 0 = No 1 = Yes
- History of Connective Tissue Diseases? _____ 0 = No 1 = Yes
- Need for continuous treatment with long term antibiotics, corticosteroids, immunosuppressive medications, H2 blockers, and or pain medications? _____ 0 = No 1 = Yes
- Legally Blind? _____ 0 = No 1 = Yes
- Unable to complete standard neuropsychological tests? _____ 0 = No 1 = Yes
- Presence of any of the following lab results? _____ 0 = No 1 = Yes
() RPR Positive, () WBC > 12,000 mcrL, () Hemoglobin < 11 g/dl,
() Creatinine > 1.5 mg/dl (except - Gilbert's disease)
() ALT, AST or alkaline phosphatase 2X upper normal limit;
() Corrected calcium < 8.5 or > 10.7 mg/dl; () Albumin < 3.4 g/dl

Unwilling to do Apheresis procedure? _____ 0 = No 1 = Yes



BLSA ID

Visit No.

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**BLSA - Screening for eligibility criteria
- Level 2 (Visit examination)**

Tester ID

Lab testing:

(1) 3ml lavender top

(1) 8ml SST top

(2) 4ml gold SST top

Urinalysis

(see order sheet for distribution)

Fasting except water since: : am
 pm

10 hour fast? Yes No

Blood draw: # attempts

Location:

- 1 - Right
- 2 - Left
- 3 - Both

- 1 - Antecubital
- 2 - Upper arm
- 3 - Lower arm
- 4 - Hand

Comment? _____

time drawn :

EKG complete? Yes
 No

initial _____ (Place EKG behind data form)

Clinically significant abnormalities? _____

Comments: _____



BLSA ID

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Visit No.

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**BLSA - Screening for eligibility criteria
- Level 2 (Visit examination)**

Tester ID

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PHYSICAL EXAMINATION (V0)

	CODE	COMMENTS
General Appearance:	<input type="radio"/> 1= Normal <input type="radio"/> 2= Abnormal <input type="radio"/> 3= Not done	
HEENT:	<input type="radio"/> 1= Normal <input type="radio"/> 2= Abnormal <input type="radio"/> 3= Not done	
Pulmonary:	<input type="radio"/> 1= Normal <input type="radio"/> 2= Abnormal <input type="radio"/> 3= Not done	
Cardiac:	<input type="radio"/> 1= Normal <input type="radio"/> 2= Abnormal <input type="radio"/> 3= Not done	
Abdomen:	<input type="radio"/> 1= Normal <input type="radio"/> 2= Abnormal <input type="radio"/> 3= Not done	
Vascular:	<input type="radio"/> 1= Normal <input type="radio"/> 2= Abnormal <input type="radio"/> 3= Not done	
Musculoskeletal:	<input type="radio"/> 1= Normal <input type="radio"/> 2= Abnormal <input type="radio"/> 3= Not done	
CNS/ Neurological	<input type="radio"/> 1= Normal <input type="radio"/> 2= Abnormal <input type="radio"/> 3= Not done	
Other:	<input type="radio"/> 1= Normal <input type="radio"/> 2= Abnormal <input type="radio"/> 3= Not done	

OBSERVED 400 METER WALK? Yes No

Comments: _____



BLSA ID

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Visit No.

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**BLSA - Screening for eligibility criteria
- Level 2 (Visit examination)**

REVIEW OF THE SYSTEMS (V0)

	CODE	Specify Abnormality	Status
HEENT:	<input type="radio"/> 1= Denies Symptoms <input type="radio"/> 2= Symptoms Reported		<input type="radio"/> 1= Resolved <input type="radio"/> 2= Ongoing
Respiratory	<input type="radio"/> 1= Denies Symptoms <input type="radio"/> 2= Symptoms Reported		<input type="radio"/> 1= Resolved <input type="radio"/> 2= Ongoing
Cardiovascular	<input type="radio"/> 1= Denies Symptoms <input type="radio"/> 2= Symptoms Reported		<input type="radio"/> 1= Resolved <input type="radio"/> 2= Ongoing
GI/GU	<input type="radio"/> 1= Denies Symptoms <input type="radio"/> 2= Symptoms Reported		<input type="radio"/> 1= Resolved <input type="radio"/> 2= Ongoing
Hepatic	<input type="radio"/> 1= Denies Symptoms <input type="radio"/> 2= Symptoms Reported		<input type="radio"/> 1= Resolved <input type="radio"/> 2= Ongoing
Musculoskeletal:	<input type="radio"/> 1= Denies Symptoms <input type="radio"/> 2= Symptoms Reported		<input type="radio"/> 1= Resolved <input type="radio"/> 2= Ongoing
Endocrine/ Metabolic	<input type="radio"/> 1= Denies Symptoms <input type="radio"/> 2= Symptoms Reported		<input type="radio"/> 1= Resolved <input type="radio"/> 2= Ongoing
Neurological	<input type="radio"/> 1= Denies Symptoms <input type="radio"/> 2= Symptoms Reported		<input type="radio"/> 1= Resolved <input type="radio"/> 2= Ongoing
Psychiatric	<input type="radio"/> 1= Denies Symptoms <input type="radio"/> 2= Symptoms Reported		<input type="radio"/> 1= Resolved <input type="radio"/> 2= Ongoing
Hematologic (i.e. bleeding)	<input type="radio"/> 1= Denies Symptoms <input type="radio"/> 2= Symptoms Reported		<input type="radio"/> 1= Resolved <input type="radio"/> 2= Ongoing
Surgery	<input type="radio"/> 1= Denies Symptoms <input type="radio"/> 2= Symptoms Reported		<input type="radio"/> 1= Resolved <input type="radio"/> 2= Ongoing
Other significant family history	<input type="radio"/> 1= Denies Symptoms <input type="radio"/> 2= Symptoms Reported		<input type="radio"/> 1= Resolved <input type="radio"/> 2= Ongoing

(* An Asterisk placed by an item indicates a related Progress note is written.

Is the screenee eligible for BLSA participation? Y N → Why?

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BLSA ID
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Visit No.
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Tester ID
[][][]

Date Completed
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BLESSED MENTAL STATUS

INTRODUCTION: "Now I would like to give you a short memory test that will take about 5 minutes. Some questions will be easy and some will be more difficult. Are you ready?" (*Examiner note: For rapid scoring, fill-in the correct answer for all items marked with an "*" , prior to test administration. Read all questions as written. If clarification is required, read the alternate text (Alt:).*)

*1. What is your name (correct name: _____)?

Participant response

Correct

Incorrect

*2. Can you tell me your age (correct age: _ _)? (Alt: Please tell me your age.)

Participant response

Correct

Incorrect

*3. When were you born (correct month, year: _____)? (Alt: In what month (year) were you born?)

Participant response

Correct

Incorrect

4. Where were you born (accept: city/town and state or country, if foreign born)? (Alt: In what city (state) were you born?)

Participant response

Correct

Incorrect

5. Where are you right now (accept: BLSA, Baltimore Longitudinal Study of Aging, Harbor Hospital, South Baltimore General Hospital, NIA ASTRA Unit)? (Alt: What is the name of this place, hospital, study, unit?)

Participant response

Correct

Incorrect

6. What street is it on (accept: Hanover Street, Cherry Hill, Reedbird, Potee, Waterview, Route 2)?

Participant response

Correct

Incorrect

*7. (Without looking at your watch), how long have you been here (correct number of hours (+/- 1) for current visit: _____)? (How many hours has it been since you arrived on the unit?)

Participant response

Correct

Incorrect

8. What city is it in (correct response: Baltimore)?

Participant response

Correct

Incorrect



BLSA ID

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Visit No.

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BLESSED MENTAL STATUS

***9. What is today's date (correct day of the month (e.g., 16th) within a day): _____)?**

Participant response

Correct

Incorrect

***10. What is the current month (correct month: _____)?**

Participant response

Correct

Incorrect

***11. What is the current year (correct year: _____)?**

Participant response

Correct

Incorrect

***12. What day of the week is today (correct day of the week: _____)?**

Participant response

Correct

Incorrect

***13. What part of the day is it (correct time of day (e.g., morning, afternoon, evening, night): _____)?**

Participant response

Correct

Incorrect

***14. Without looking at a watch or clock, give me your best guess about what time it is (correct time (within one hour of start time: _____)).**

Participant response

Correct

Incorrect

***15. What season is this (correct season #(e.g., spring, summer, fall, winter within a day: _____)?**

Participant response

Correct

Incorrect

#note: The "official" dates of the change of seasons vary from year to year. We have indicated what the dates of the change of seasons tend to be. Accept one day on either side of the actual change of the season. For example, if the first day of Winter is December 21st, a participant will get that item correct if s/he says either Fall or Winter on December 20th, 21st or 22nd.

Spring: begins March 20 (accept either Winter or Spring from March 19 to March 21)

Summer: begins June 21st (accept either Spring or Summer from June 20 to June 22)

Fall: begins September 23 (accept either Summer or Fall from September 22 to September 24)

Winter: begins December 21 (accept either Fall or Winter from December 20 to December 22)



BLSA ID
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Visit No.
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BLESSED MENTAL STATUS

INSTRUCTIONS: "Now I'm going to tell you a name and address that I would like you to remember for later. After I give you the name and address, I want you to repeat it right back to me to make sure you heard it correctly. Ready? Here it is (*speak clearly and slowly*):" **John Brown, 42 Market Street, Chicago** If the participant does not voluntarily repeat the name and address, *say: "What did I just say?"* *If the participant cannot repeat the full name and address, say "Let's try that again. Repeat after me: John Brown. (Your turn.) 42 Market Street. (Your turn.) Chicago. (Your turn.)"* *If the participant cannot repeat each component correctly, provide the name and address again, one word at a time. Record outcome below.*

When did the participant correctly repeat John Brown, 42 Market Street, Chicago?

First time When given in 3 phrases When given in single words Could not repeat

16. What is your mother's first name (accept: anything resembling a first name)?

Participant response

Correct

Incorrect

17. How much schooling did you have (accept: number of years or number or type of degrees)?

Participant response

Correct

Incorrect

18. What is the name of one specific school that you attended (accept: anything reasonable)?

Participant response

Correct

Incorrect

19. What kind of work have you done (accept: anything reasonable)?

Participant response

Correct

Incorrect

20. Can you tell me who the president of the United States is right now (correct president: _____)?

Participant response

Correct

Incorrect

21. Who was the president before (Mr. Obama) (correct previous president: _____)?

Participant response

Correct

Incorrect

22. Can you tell me one of the years of World War I (accept: any year from 1914 to 1918)?

Participant response

Correct

Incorrect



Mini-Mental State Examination (MMSE) (Administration Sheet):

Now I am going to ask you some more questions.

(WRITE PARTICIPANT'S RESPONSES IN THE SPACE PROVIDED. COMPLETE ALL SCORING AFTER QUESTIONNAIRE ADMINISTRATION. TRANSFER SCORES TO MMSE SCORE SHEET) Score 1 = correct, 0 = incorrect, 9_ = missing

___ ^Where are you right now? (Alt: What is the name of this place? Or What is the name of the study?) _____
(ACCEPT: BLSA, BALTIMORE LONGITUDINAL STUDY ON AGING, HARBOR HOSP., SOUTH BALTIMORE GENERAL HOSPITAL, NIA ASTRA UNIT)

___ ^^What is the name of the street that we are on? _____
(ACCEPT: HANOVER ST., CHERRY HILL, REEDBIRD, POTEE WATERVIEW, ROUTE 2)

___ What floor are we on? _____ (ACCEPT: 5TH)

___ ^^Without looking at your watch, how long have you been here? _____
(ALT: HOW MANY HOURS HAS IT BEEN SINCE YOUR ARRIVED ON THE UNIT?) record response _____ (correct number of hours (+/- 1 hr) for current visit: _____)

___ ^What city are we in? _____

___ What county do you live in? _____

___ What state are we in? _____

I am going to give you a little test of memory. I am going to say 3 words and after I am finished saying all three I want you to repeat them back to me, and then remember them for later (look down, then back up and say the following 3 words using a 1 second pace): Ball .. Flag .. Tree. Number of trials _____

(The first repetition determines the score. However, keep saying all 3 until s/he repeats all 3, up to 6 tries. If s/he does not eventually learn all 3, do not administer the recall).

___ Ball

___ Flag

___ Tree

(^These items overlap between the BIMC and MMSE. Administer them during the MMSE only, but add the score to each the BIMC and MMSE.

^^These items are from the BIMC. Administer them during the MMSE, but add the score to the BIMC.)

___ Now I would like you to spell the word **WORLD**, backwards. _____

___ D

___ L

___ R

___ O

___ W

(Only have S spell WORLD forward if S has extreme difficulty spelling world backwards - then have S spell WORLD forward.)

Now I would like you to recall the 3 words I asked you to remember earlier.

___ Ball

___ Flag

___ Tree

Next, what is this *(show the participant your wristwatch)*, **and what is this** *(show the participant a pencil)*.

___ Wristwatch

___ Pencil

___ **Now I am going to say a phrase and when I am finished I would like you to repeat it back to me exactly as I say it** *(look down, then back up and say):*

No ifs, ands, or buts. *(The repetition must be exactly as read to be correct.)*

Next I would like you to take this sheet of paper in your right hand, fold it in half, and place it on the floor. *(Hold the paper up along the long end of the paper, so that the participant can see it, but out of his/her reach. Wait until you have finished all 3 phases of the command, and then hand the paper to the participant midline – not off to the right or left.)*

___ Right hand

___ Fold in half

___ Place on floor

____ Now I would like you to do what this says. (Show participant the sheet with "Close your eyes " on it. After the participant closes his/her eyes, say): **You may open them.**

____ Now I would like you to write a sentence on this page. (Give participant the sheet that says "sentence" in the upper right hand corner.) **You may write any sentence that you want, and you have some pencils right there.** (point to the 3 pencils that are next to the participant.)

('Write a sentence' should be presented aurally rather than written. Only present it in written form if the subject is deaf, or very hard of hearing. If it is presented in written form do not have a line for the sentence because it restricts the subject's responding.)

____ Now I would like you to copy this design, as much like it as you can, anywhere on the page.

(Give participant the sheet with the Intersecting pentagons' on it.)