# SPRINT - Annual Medications and Physical Exam History Form

Participant Name: _____

Participant ID: ___ ___ ___ ___ ___ ___ ___ ___

Visit: ASK Site: ___ ___ ___

Date of Visit: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

Form Completed by: __ __ __ __

Date Entered: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

Data Entered by: __ __ __ __

## Medication Inventory

1. We are interested in the **prescription** medications you are using. We are particularly interested in medications your doctor prescribed for you and were filled by a pharmacist. These include pills, skin patches, eye drops, creams, salves, and injections. This does not include blood pressure medications. The letter you received about this appointment asked you to bring them to the clinic.

   For prescriptions that you took in the last two weeks, did you bring all of the prescription medications or a list of the prescription medications from your pharmacy or physician?

   ☐ Yes
   ☐ Took no meds
   ☐ Refused/No

   **Note for clinic staff:** If a participant didn't bring their medications or a list of their medications, is a list of prescription medications available to the clinic staff via EMR?

RECORD NAME OF MEDICATION ONLY, not the dose or strength

| | | | |
|---|---|---|---|
| 1. | | 11. | |
| 2. | | 12. | |
| 3. | | 13. | |
| 4. | | 14. | |
| 5. | | 15. | |
| 6. | | 16. | |
| 7. | | 17. | |
| 8. | | 18. | |
| 9. | | 19. | |
| 10. | | 20. | |

RECORD ADDITIONAL MEDICATIONS ON THE BACK OF THE PAGE

2. ☐ Check here if participant is unable to stand for measurements (e.g., wheelchair-bound)

Participant Weight: Record measurement in pounds __ __ __.__

3. Arm circumference __ __ cm

Check appropriate cuff size

☐ Small (17- 22 cm) ☐ Medium (22-32 cm) ☐ Arm > 50 cm (use manual cuff)

☐ Large (32-42 cm) ☐ Extra Large (42-50 cm)

4. Do you now smoke cigarettes?

☐ Every day or some days ☐ Not at all ☐ Don't Know ☐ Refuse to answer

5. Since you have been part of the SPRINT study (date), has a doctor or other health professional told you that you have diabetes?
*(Interviewer, confirm that the diagnosis occurred since screening/RZ)*

☐ No
☐ Yes
☐ Unknown

6. How is your diabetes being treated?
Check all that apply:

a. ☐ Pills or tablets
b. ☐ Insulin shots
c. ☐ Diet and/or exercise

7. What is your marital status?

☐ Married
☐ Living in a marriage-like relationship
☐ Widowed
☐ Divorced
☐ Separated
☐ Never married

8. Do you use aspirin on a daily basis?

☐ Yes
☐ No

9. Do you use ibuprofen, naproxen sodium, or other non-steroidal anti-inflammatory medication on a daily basis?

☐ Yes
☐ No

10. Was physical exam performed ? ☐ Yes ☐ No

| If No, reason: | |
|---|---|

# SPRINT - Annual Medications and Physical Exam History Form

| | | | |
|---|---|---|---|
| Participant Name: | _____ | Date of Visit: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| Participant ID: | ___ ___ ___ ___ ___ ___ ___ ___ | Form Completed by: | __ __ __ __ |
| Visit: ASK | Site: ___ ___ ___ | Date Entered: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| | | Data Entered by: | __ __ __ __ |

**Medication Inventory**

1. We are interested in the **prescription** medications you are using. We are particularly interested in medications your doctor prescribed for you and were filled by a pharmacist. These include pills, skin patches, eye drops, creams, salves, and injections. This does not include blood pressure medications. The letter you received about this appointment asked you to bring them to the clinic.

   For prescriptions that you took in the last two weeks, did you bring all of the prescription medications or a list of the prescription medications from your pharmacy or physician?

   ☐ Yes
   ☐ Took no meds
   ☐ Refused/No

   **Note for clinic staff:** If a participant didn't bring their medications or a list of their medications, is a list of prescription medications available to the clinic staff via EMR?

RECORD NAME OF MEDICATION ONLY, not the dose or strength

| | | | |
|---|---|---|---|
| 1. | | 11. | |
| 2. | | 12. | |
| 3. | | 13. | |
| 4. | | 14. | |
| 5. | | 15. | |
| 6. | | 16. | |
| 7. | | 17. | |
| 8. | | 18. | |
| 9. | | 19. | |
| 10. | | 20. | |

RECORD ADDITIONAL MEDICATIONS ON THE BACK OF THE PAGE

2. ☐ Check here if participant is unable to stand for measurements (e.g., wheelchair-bound)

Participant Weight: Record measurement in pounds __ __ __.__

3. Arm circumference __ __ cm

Check appropriate cuff size

☐ Small (17- 22 cm) ☐ Medium (22-32 cm) ☐ Arm > 50 cm (use manual cuff)

☐ Large (32-42 cm) ☐ Extra Large (42-50 cm)

4. Do you now smoke cigarettes?

☐ Every day or some days ☐ Not at all ☐ Don't Know ☐ Refuse to answer

5. Since you have been part of the SPRINT study (date), has a doctor or other health professional told you that you have diabetes?
*(Interviewer, confirm that the diagnosis occurred since screening/RZ)*

☐ No
☐ Yes
☐ Unknown

6. How is your diabetes being treated?
Check all that apply:

a. ☐ Pills or tablets
b. ☐ Insulin shots
c. ☐ Diet and/or exercise

7. What is your marital status?

☐ Married
☐ Living in a marriage-like relationship
☐ Widowed
☐ Divorced
☐ Separated
☐ Never married

8. Do you use aspirin on a daily basis?

☐ Yes
☐ No

9. Do you use ibuprofen, naproxen sodium, or other non-steroidal anti-inflammatory medication on a daily basis?

☐ Yes
☐ No

## 4-meter Walk

**Script:**

**Now I am going to observe how you normally walk. If you use a cane or other walking aid and you feel you need it to walk a short distance, then you may use it.**

**This is our walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store.**

*Demonstrate the walk for the participant.*

**Walk all the way past the other end of the tape before you stop. I will walk with you. Do you feel this would be safe?**

*Have the participant stand with both feet touching the starting line.*

**When I want you to start, I will say: "Ready, begin."** *When the participant acknowledges this instruction say:* **"Ready, begin."**

*Press the start/stop button to start the stopwatch when the participant begins to move.*

*Walk behind and to the side of the participant.*

*Stop timing when one of the participant's feet is completely across the end line. Record time for first trial.*

**Now I want you to turn around and repeat the test. When I want you to start, I will say: "Ready, begin."** *When the participant acknowledges this instruction say:* **"Ready, begin."**

*Complete the walk test as before. Record time for second trial.*

| | |
|---|---|
| 10. Time: | TRIAL 1: __ __.__ __ sec<br>TRIAL 2: __ __.__ __ sec |
| 11. If the participant did not attempt test:<br>(Select one reason) | a. ☐ Tried but unable<br>b. ☐ Participant could not walk unassisted<br>c. ☐ Not attempted, staff felt unsafe<br>d. ☐ Not attempted, participant felt unsafe<br>e. ☐ Participant unable to understand instructions<br>f. ☐ Other (specify) _____<br>g. ☐ Participant refused |
| 12. Aids used for walk: | a. ☐ None<br>b. ☐ Cane<br>c. ☐ Other (specify) _____ |
| 13. Was physical exam performed ? | ☐ Yes ☐ No |
| If No, reason: | |

# SPRINT - Self-Administered Baseline History

| | | | |
|---|---|---|---|
| Participant Name: | _____ | Date of Visit: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| Participant ID: | ___ ___ ___ ___ ___ ___ ___ ___ | Form Completed by: | __ __ __ __ |
| Visit: ASK | Site: ___ ___ ___ | Date Entered: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| | | Data Entered by: | |

## Demographics

**1.** Do you live with one or more other adults?

- ☐ Yes
- ☐ No

**2.** Which category below best describes the highest level of formal education you completed?

- ☐ Did not go to school
- ☐ Grade School (1-4 years)
- ☐ Grade School (5-8 years)
- ☐ Some High School (9-11 years)
- ☐ High School diploma or G.E.D.
- ☐ Business/Vocational training school after high school graduation
- ☐ Some College (no degree obtained)
- ☐ Associate Degree (A.D. or A.A.)
- ☐ College Graduate
- ☐ Some College or professional school after college graduation
- ☐ Master's Degree
- ☐ Doctoral Degree (Ph.D., M.D., J.D., etc.)

## Employment

**3.** Are you working full time for pay?

- ☐ Yes, Skip to Question 5.
- ☐ No

**4.** If no, please mark all that apply:

- ☐ Retired
- ☐ Working part time for pay
- ☐ Keeping house or raising children or grandchildren full time
- ☐ Unemployed or laid off
- ☐ Looking for work

## Insurance Status

**5.** Which of the following describes your current type of insurance coverage?

- ☐ Medicare
- ☐ Medicaid
- ☐ VA
- ☐ Private/Other
- ☐ Uninsured, Skip to Question 8.

**6.** Do you have full or partial drug benefits under your insurance or health plan?

- ☐ Yes
- ☐ No
- ☐ Don't Know
- ☐ Other
- ☐ Uninsured

**7.** What type of health insurance do you have? (Please check all that apply)

- ☐ Have to pay a co-payment for doctor's visits or emergency room visits
- ☐ Have to get a referral to see a specialist
- ☐ Neither. No co-payments or referral for specialist required
- ☐ Don't Know

**8.** Which of the following health care facilities best describes your usual source of care? (check one)?

- ☐ Private doctor's office
- ☐ Hospital clinic or outpatient department
- ☐ Community health center
- ☐ Other kind of health care facility
- ☐ No usual source of care

| Have you ever been told by a physician that you have: | | |
|---|---|---|
| **9. atrial fibrillation** or **atrial flutter** | ☐ Yes | ☐ No |
| **10.** blockage in the blood flow to your heart, also called **coronary artery disease** ; such blockage can lead to chest pain, also called **angina** | ☐ Yes | ☐ No |
| **11.** a **heart attack** | ☐ Yes | ☐ No |
| **12.** a weak heart, also called **congestive heart failure** or "fluid on the lungs" | ☐ Yes | ☐ No |
| **13.** an **irregular heart beat** | ☐ Yes | ☐ No |
| **14.** ulcer of your stomach or duodenum, such as **gastric or peptic ulcer** | ☐ Yes | ☐ No |
| **15. Crohn's disease, ulcerative colitis, or inflammatory bowel disease** | ☐ Yes | ☐ No |
| **16. diverticulitis** | ☐ Yes | ☐ No |
| **17. chronic hepatitis or cirrhosis of the liver** | ☐ Yes | ☐ No |
| **18. gallbladder disease or gallstones** | ☐ Yes | ☐ No |
| **19. kidney or bladder infections** | ☐ Yes | ☐ No |
| **20. enlarged prostate, also called Benign Prostatic Hypertrophy (BPH)** | ☐ Yes | ☐ No |
| **21. infection of the prostate, also called prostatitis** | ☐ Yes | ☐ No |
| **22. osteoarthritis or degenerative arthritis** | ☐ Yes | ☐ No |
| **23. rheumatoid arthritis** | ☐ Yes | ☐ No |
| **24. gout** | ☐ Yes | ☐ No |
| **25. any other type of arthritis** | ☐ Yes | ☐ No |
| **26. hip problems** | ☐ Yes | ☐ No |
| **27. cancer** (Do not include skin cancer, except if it was **Melanoma**) | ☐ Yes | ☐ No |
| **28. skin cancer** | ☐ Yes | ☐ No |
| **29. blockages in the blood vessels, arteries to your legs, also called peripheral vascular disease (PVD)** | ☐ Yes | ☐ No |
| **30. a seizure disorder** | ☐ Yes | ☐ No |
| **31. a stroke** | ☐ Yes | ☐ No |
| **32. TIA, also called "Transient Ischemic Attack", or "warning stroke"** | ☐ Yes | ☐ No |
| **33. thyroid disease** | ☐ Yes | ☐ No |
| **34. anemia** or low blood count | ☐ Yes | ☐ No |
| **35. diabetes** or high blood sugar | ☐ Yes | ☐ No |
| **36. hypertension** or high blood pressure | ☐ Yes | ☐ No |
| **37. low back pain** | ☐ Yes | ☐ No |
| **38. cataracts** | ☐ Yes | ☐ No |

| Have you ever been **treated for:** | | |
|---|---|---|
| **39. Schizophrenia** | ☐ Yes | ☐ No |
| **40. Depression** | ☐ Yes | ☐ No |
| **41. Bipolar Disorder or Manic Depressive Disorder** | ☐ Yes | ☐ No |
| **42. Anxiety or Panic Disorder** | ☐ Yes | ☐ No |
| **43. Post Traumatic Stress Disorder or PTSD** | ☐ Yes | ☐ No |
| **44. Alcohol Abuse** | ☐ Yes | ☐ No |

## Family History

**45.** Is there a history of heart disease, heart attack, or stroke in a child, brother, sister, or parent?

☐ Yes ☐ No ☐ Unknown

If yes, were any of these events before age 55 in men; before age 65 in women?

☐ Yes ☐ No ☐ Unknown

## Health Habits

**46.** During the last 12 months, did you drink any alcohol?

☐ Yes ☐ No ☐ Don't Know ☐ Refuse to Answer

*(If no, skip to Question 51)*

**47.** During the last 12 months, how often did you usually have any kind of drink containing alcohol? By a drink we mean half an ounce of absolute alcohol (e.g. a 12 ounce can or glass of beer or cooler, a 5 ounce glass of wine, or a drink containing 1 shot of liquor).

Did you have one drink or more every day?

☐ Yes ☐ No ☐ Don't Know ☐ Refuse to Answer

If no, choose one time interval and fill in the blank for the number of times you had any kind of drink containing alcohol.

_____ times each week
_____ times each month
_____ times each year

**48.** During the last 12 months, how many alcoholic drinks did you have on a typical day when you drank alcohol?

_____ drinks(s)

**49.** (FOR MEN) During the last 12 months, how often did you have 5 or more drinks containing any kind of alcohol within a two-hour period?

Did you have 5 or more drinks within a two-hour period every day?

☐ Yes ☐ No ☐ Don't Know ☐ Refuse to Answer

If no, choose one time interval and fill in the blank for the number of times you had 5 or more drinks containing alcohol within a two-hour period. **If in the last 12 months you *never* had 5 or more drinks within a two-hour period, place a '0' beside 'times each year'.**

_____ times each week
_____ times each month
_____ times each year

**50.** (FOR WOMEN) During the last 12 months, how often did you have 4 or more drinks containing any kind of alcohol within a two-hour period?

Did you have 4 or more drinks within a two-hour period every day?

☐ Yes ☐ No ☐ Don't Know ☐ Refuse to Answer

If no, choose one time interval and fill in the blank for the number of times you had 4 or more drinks containing alcohol within a two-hour period. **If in the last 12 months you *never* had 4 or more drinks within a two-hour period, place a '0' beside 'times each year'.**

_____ times each week
_____ times each month
_____ times each year

## Tobacco Questions

**51.** Have you smoked at least 100 cigarettes in your entire life?

☐ Yes ☐ No ☐ Don't Know ☐ Refuse to Answer

*(If no, skip to question 54)*

**52.** How old were you when you first started to smoke cigarettes fairly regularly?
Enter age in years ____ ____

**53.** Do you <u>now</u> smoke cigarettes?

_____ YES, every day or some days. (Answer question 'a'.)

a. About how many cigarettes do you usually smoke each day? (One pack equals 20 cigarettes. If you smoke less than one cigarette each day, record 1 on the line.

_____ Record number of cigarettes each day

_____ NO,not at all. (Answer questions 'b and c'.)

b. How old were you when you last smoked cigarettes fairly regularly?

_____ Record age in years.

c. At that time, about how many cigarettes did you usually smoke each day? (One pack equals 20 cigarettes. If you smoked less than one cigarette each day, record 1 on the line.

_____ Record number of cigarettes each day

## Physical Activity

The next question is about vigorous activity. When we say "vigorous" we mean activities that make you sweat, increase your heart rate or increase your breathing. Please think about vigorous activities that you may have done at home or at places of work other than your home, as well as vigorous recreational activities or conditioning exercises.

**54.** Please think over the last year and indicate how often you participate in vigorous activities.

- ☐ rarely or never
- ☐ 1-3 times per month
- ☐ 1 time per week
- ☐ 2-4 times per week
- ☐ 5+ times per week

Now let's think about less vigorous activities like brisk walking, climbing stairs or vacuuming floors. Don't include activities like standing still or walking slowly. Again, include work time, free time, and time at home.

**55.** On average, how much time do you spend doing these less vigorous activities?

- ☐ 0-15 minutes per day
- ☐ 15-30 minutes per day
- ☐ 30-60 minutes per day
- ☐ 1-4 hours per day
- ☐ 4 or more hours per day

**56.** Do you use aspirin on a daily basis?

- ☐ Yes
- ☐ No

**57.** Do you use ibuprofen, naproxen sodium, or other non-steroidal anti-inflammatory medication on a daily basis?

- ☐ Yes
- ☐ No

# SPRINT - Baseline Medications and Physical Exam Form

Participant Name: _____

Participant ID: ___ ___ ___ ___ ___ ___ ___ ___

Visit: ASK Site: ___ ___ ___

Date of Visit: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

Form Completed by: __ __ __ __

Date Entered: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

Data Entered by: __ __ __ __

1. We are interested in the prescription medications you are using. We are particularly interested in medications your doctor prescribed for you and were filled by a pharmacist. These include pills, skin patches, eye drops, creams, salves, and injections. This does not include blood pressure medications. The letter you received about this appointment asked you to bring them to the clinic.

   Did you bring all of the prescription medications that you took in the last two weeks?

   ☐ Yes
   ☐ Took no meds
   ☐ Refused

RECORD NAME OF MEDICATION ONLY, not the dose or strength

| | | | |
|---|---|---|---|
| 1. | | 11. | |
| 2. | | 12. | |
| 3. | | 13. | |
| 4. | | 14. | |
| 5. | | 15. | |
| 6. | | 16. | |
| 7. | | 17. | |
| 8. | | 18. | |
| 9. | | 19. | |
| 10. | | 20. | |

RECORD ADDITIONAL MEDICATIONS ON THE BACK OF THE PAGE

2. ☐ Check here if participant is unable to stand for measurements (e.g., wheelchair-bound)

Participant Weight: Record measurement in pounds __ __ __.__

Participant Height: Record measurement in inches __ __ __.__

3. What is your marital status?

- ☐ Married
- ☐ Living in a marriage-like relationship
- ☐ Widowed
- ☐ Divorced
- ☐ Separated
- ☐ Never married

4. Was physical exam performed ? ☐ No ☐ Yes

If No, reason:

# SPRINT - Baseline Medications and Physical Exam Form

Participant Name: _____

Participant ID: ___ ___ ___ ___ ___ ___ ___ ___

Visit: ASK Site: ___ ___ ___

Date of Visit: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

Form Completed by: __ __ __ __

Date Entered: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

Data Entered by: __ __ __ __

1. We are interested in the prescription medications you are using. We are particularly interested in medications your doctor prescribed for you and were filled by a pharmacist. These include pills, skin patches, eye drops, creams, salves, and injections. This does not include blood pressure medications. The letter you received about this appointment asked you to bring them to the clinic.

   Did you bring all of the prescription medications that you took in the last two weeks?

   ☐ Yes
   ☐ Took no meds
   ☐ Refused

RECORD NAME OF MEDICATION ONLY, not the dose or strength

| | | | |
|---|---|---|---|
| 1. | | 11. | |
| 2. | | 12. | |
| 3. | | 13. | |
| 4. | | 14. | |
| 5. | | 15. | |
| 6. | | 16. | |
| 7. | | 17. | |
| 8. | | 18. | |
| 9. | | 19. | |
| 10. | | 20. | |

RECORD ADDITIONAL MEDICATIONS ON THE BACK OF THE PAGE

2. ☐ Check here if participant is unable to stand for measurements (e.g., wheelchair-bound)

Participant Weight: Record measurement in pounds __ __ __.__

Participant Height: Record measurement in inches __ __ __.__

3. What is your marital status?

- ☐ Married
- ☐ Living in a marriage-like relationship
- ☐ Widowed
- ☐ Divorced
- ☐ Separated
- ☐ Never married

4. Was physical exam performed ? ☐ No ☐ Yes

| If No, reason: | |
|---|---|

## 4-meter Walk

**Script:**

**Now I am going to observe how you normally walk. If you use a cane or other walking aid and you feel you need it to walk a short distance, then you may use it.**

**This is our walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store.**

*Demonstrate the walk for the participant.*

**Walk all the way past the other end of the tape before you stop. I will walk with you. Do you feel this would be safe?**

*Have the participant stand with both feet touching the starting line.*

**When I want you to start, I will say: "Ready, begin."** *When the participant acknowledges this instruction say:* **"Ready, begin."**

*Press the start/stop button to start the stopwatch when the participant begins to move.*

*Walk behind and to the side of the participant.*

*Stop timing when one of the participant's feet is completely across the end line. Record time for first trial.*

**Now I want you to turn around and repeat the test. When I want you to start, I will say: "Ready, begin."** *When the participant acknowledges this instruction say:* **"Ready, begin."**

*Complete the walk test as before. Record time for second trial.*

| | |
|---|---|
| 5. Time: | TRIAL 1: __ __.__ __ sec<br>TRIAL 2: __ __.__ __ sec |
| 6. If the participant did not attempt test: (Select one reason) | a. ☐ Tried but unable<br>b. ☐ Participant could not walk unassisted<br>c. ☐ Not attempted, staff felt unsafe<br>d. ☐ Not attempted, participant felt unsafe<br>e. ☐ Participant unable to understand instructions<br>f. ☐ Other (specify) _____<br>g. ☐ Participant refused |
| 7. Aids used for walk: | a. ☐ None<br>b. ☐ Cane<br>c. ☐ Other (specify) _____ |

# SPRINT BP Management Form - Baseline

Participant Name: _____

Participant ID: ___ ___ ___ ___ ___ ___ ___ ___

Visit: ASK Site: ___ ___ ___

Date of Visit: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

Form Completed by: __ __ __ __

Date Entered: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

Data Entered by:

**Part A. Current Blood Pressure (Cuff Size used at _____ was _____ )**

1. ☐ Check here if measurement was not performed using the study automated device.

Seated Measurements

| | Systolic | Diastolic | Heart Rate |
|---|---|---|---|
| 1st | _____ mmHg | _____ mmHg | _____ bpm |
| 2nd | _____ mmHg | _____ mmHg | _____ bpm |
| 3rd | _____ mmHg | _____ mmHg | _____ bpm |
| Average | _____ mmHg | _____ mmHg | _____ bpm |

2. ☐ Check here and **STOP** if participant is unable to stand.

Standing Measurement (@ 1 minute)

| Systolic | Diastolic | Heart Rate |
|---|---|---|
| _____ mmHg | _____ mmHg | _____ bpm |

3. Did participant experience dizziness or light headed feelings when standing for this exam?

☐ No

☐ Yes

# SPRINT - Blood Pressure Medication Management Log

Participant Name: _____

Participant ID: ___ ___ ___ ___ ___ ___ ___ ___

Visit: ASK Site: ___ ___ ___

Date of Visit: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

Form Completed by: __ __ __ __

Date Entered:

Data Entered by:

## Part A. Number of Medications

1. Number of medications prescribed at last visit ? _____
   Last visit _____ on __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

2. Number of medications prescribed at exit for this visit ? _____
   Note: if response to both (1) and (2) are zero, **STOP HERE**.

## Part B. Medications / Doses

| Name | Average Total Daily Dose | Units | Single Daily Dose? | Date Started (mm/dd/yyyy) | Continuing? | Date Stopped (mm/dd/yyyy) | Stopped due to AE ?* |
|---|---|---|---|---|---|---|---|
| | | | ☐ No | | ☐ Yes | | ☐ Yes |
| **Notes:** | | | | | | | |
| | | | ☐ No | | ☐ Yes | | ☐ Yes |
| **Notes:** | | | | | | | |
| | | | ☐ No | | ☐ Yes | | ☐ Yes |
| **Notes:** | | | | | | | |
| | | | ☐ No | | ☐ Yes | | ☐ Yes |
| **Notes:** | | | | | | | |
| | | | ☐ No | | ☐ Yes | | ☐ Yes |
| **Notes:** | | | | | | | |

*If the investigator feels the adverse experience meets the definition of an SAE, a Serious Adverse Experience form must be completed within 72 hours of event notification. A serious adverse experience (SAE) is defined as any adverse experience that is significantly life threatening and/or results in death, permanent disability, hospitalization or prolongation of hospitalization.*

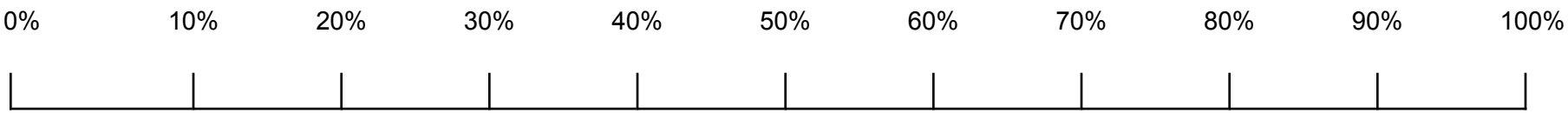
| Name | Average Total Daily Dose | Units | Single Daily Dose? | Date Started (mm/dd/yyyy) | Continuing? | Date Stopped (mm/dd/yyyy) | Stopped due to AE ?* |
|---|---|---|---|---|---|---|---|
| | | | ☐ No | | ☐ Yes | | ☐ Yes |
| **Notes:** | | | | | | | |
| | | | ☐ No | | ☐ Yes | | ☐ Yes |
| **Notes:** | | | | | | | |
| | | | ☐ No | | ☐ Yes | | ☐ Yes |
| **Notes:** | | | | | | | |
| | | | ☐ No | | ☐ Yes | | ☐ Yes |
| **Notes:** | | | | | | | |
| | | | ☐ No | | ☐ Yes | | ☐ Yes |
| **Notes:** | | | | | | | |

*If the investigator feels the adverse experience meets the definition of an SAE, a Serious Adverse Experience form must be completed within 72 hours of event notification. A serious adverse experience (SAE) is defined as any adverse experience that is significantly life threatening and/or results in death, permanent disability, hospitalization or prolongation of hospitalization.*

## Part C. Adherence (skip if Part A, Question 1: Number of medications prescribed at last visit = 0)

1. Many people do not take their medications 100% of the time. On the line below, 0% means you have taken none of your blood pressure pills since your last visit as they were prescribed for you; 50% means you have taken half of your blood pressure pills as prescribed for you since your last visit; and 100% means you have taken every single dose of your blood pressure pills as prescribed for you since your last visit.

   **Please circle the percentage below that shows your best guess about how many days you have taken all of your blood pressure medications as prescribed since your last visit**



# SPRINT - Encounter & Disposition - Closeout

Participant Name: _____
Participant ID: ___ ___ ___ ___ ___ ___ ___ ___
Visit: ASK Site: ___ ___ ___

Date of Visit: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)
Form Completed by: __ __ __ __
Date Entered: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)
Data Entered by: __ __ __ __

## Part I. Contact Type

1. Was study data collected for this visit?

0 ☐ No (Complete Part III, IV, and VI)

1 ☐ Yes

If yes, what type of contact is this?

1 ☐ Clinic

2 ☐ Home

3 ☐ Phone

4 ☐ Proxy (skip to Part III)

5 ☐ Other (Please specify): _____

## Part II. Health Information

2. Do you have a healthcare provider for your health needs after the end of the study?

0 ☐ No (Provide participant with "Tips for Finding a Healthcare Provider and Insurance" document then SKIP to Question 3)

1 ☐ Yes

If Yes, confirm PCP Contact Information on the Participant Contact Form is current.

Prior to this visit, has care for blood pressure treatment management been transitioned to the participant's health care provider?

0 ☐ No

1 ☐ Yes

3. Which of the following describes your current type of insurance coverage (mark all that apply)?

1 ☐ Medicare

2 ☐ Medicaid

3 ☐ VA

4 ☐ Affordable Care Act

5 ☐ Private/Other (including Medicare supplement, if applicable)

6 ☐ Uninsured (Provide participant with "Tips for Finding a Healthcare Provider and Insurance" document)

4. How old were you when you were first told by a health care provider that you have high blood pressure? (for women: while you were not pregnant)?

_____ Age (in years)

5. Prior to enrollment in SPRINT, had you ever been prescribed medications for high blood pressure? (for women: while you were not pregnant)?

0 ☐ No

1 ☐ Yes

If Yes, indicate the age when you began taking blood pressure medications.

_____ Age (in years)

6. Since you joined SPRINT on *date of randomization*, for health reasons, have you stayed in a nursing or rehabilitation facility one or more times?

0 ☐ No (skip to Part III)

1 ☐ Yes

If Yes, were you there for a total of

1 ☐ 100 days or less

2 ☐ More than 100 days

If you have stayed in a nursing or rehabilatition facility one or more times since joining SPRINT, how many times have you stayed in one? _____

Do you currently reside in either an assisted living facility or nursing home?

0 ☐ No

1 ☐ Yes (if yes, update Participant Contact Information Form)

## Part III. Participant Materials Checklist

7. Check each item off as given/mailed to participant

- 1 ☐ Participant Bulletin
- 2 ☐ Certificate of Appreciation
- 3 ☐ SPRINT jar opener
- 4 ☐ SPRINT Medical Summary Report (participant copy)
- 5 ☐ SPRINT Medical Summary Report (health care provider copy)
- 6 ☐ Health Care Provider Letter
- 7 ☐ GAP Information (medication sheets and assistance applications, if applicable)
- 8 ☐ 3-month supply of study medication dispensed (if applicable)

If no materials were given/mailed to participant check here ☐

## Part IV. End of Study Final Visit Summary

8. Has the participant signed the SPRINT Addendum to the Informed Consent?

- 0 ☐ No (If no, indicate reason for refusal below)
  - 1 ☐ Participant not interested in future contact about extension or follow-up studies
  - 2 ☐ Undecided/Needs additional time to review
  - 3 ☐ Other - Please specify _____
- 1 ☐ Yes

(If yes, date signed ___/___/_____ )

9. Has the participant signed an updated Medical Release document?

- 0 ☐ No
- 1 ☐ Yes

## Part V. Completed Visits

10. Indicate the forms/data that were collected at this visit:

Note that forms highlighted in grey are not expected to be completed at the closeout visit for this participant.

| | Collected? No | Yes |
|---|---|---|
| Events Ascertainment Form | ☐ | ☐ |
| Close-out Blood Pressure Management Form | ☐ | ☐ |
| BP Medication Log | ☐ | ☐ |
| Participant Contact Information Form | ☐ | ☐ |
| Close-out Lab Shipment Form (A or B) | ☐ | ☐ |
| MRI CBC Lab Shipment form (only subsample) | ☐ | ☐ |
| MRI Screening Form (only subsample) | ☐ | ☐ |
| Annual History and Physical Exam Form | ☐ | ☐ |
| My Health Form | ☐ | ☐ |
| Men's/Women's Health Form (only subsample) | ☐ | ☐ |
| Falls Self Efficacy Form (only subsample) | ☐ | ☐ |
| Morisky/Patient Satisfaction | ☐ | ☐ |
| ECG | ☐ | ☐ |
| Drug Dispensing Form | ☐ | ☐ |

11. Were the MIND Screening or MIND Extended Battery forms included in the packet for this visit or did you manually print them out?

0 ☐ No (STOP)

1 ☐ Yes

If yes, did you complete any MIND testing?

0 ☐ No (complete MIND Cover Page(s) only)

1 ☐ Yes

If yes, indicate the tests that were collected at this visit:

1 ☐ MIND Screening Battery

2 ☐ MIND Extended Battery

## Part VI. Missed Visits

12. Indicate below the reason the visit was missed

1 ☐ Participant cannot be located

2 ☐ Participant located but unable to make contact or collect data

3 ☐ Participant is hospitalized (document in source notes when, where and why participant was admtted. Complete an SAE form if not previously completed and gather materials for event adjudication.)

4 ☐ Participant died (complete an SAE form)

5 ☐ Scheduling conflict

6 ☐ Participant withdrew consent (Complete a Participant Status Log)

7 ☐ Other, please specify _____

# SPRINT - Encounter and Disposition

| | | | |
|---|---|---|---|
| Participant Name: | _____ | Date of Visit: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| Participant ID: | ___ ___ ___ ___ ___ ___ ___ ___ | Form Completed by: | __ __ __ __ |
| Visit: ASK | Site: ___ ___ ___ | Date Entered: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| | | Data Entered by: | |

## Part A. Activity Status

1. Are the participant's blood pressure (BP) and antihypertensive therapy being managed by study clinicians or co-managed with another non-study clinician? See Protocol Adherence Flowchart in Chapter 11 of the SPRINT MOP.

   0 ☐ No, participant is BP inactive

   1 ☐ Yes, participant is BP active

   If no, indicate reason(s) for BP inactivity (check all that apply):

   - ☐ Participant dissatisfied with treatment arm assignment
   - ☐ Participant dissatisfied with study formulary
   - ☐ Participant dissatisfied with visit schedule
   - ☐ Participant has new health problem since randomization
   - ☐ Participant cannot be seen in clinic on schedule such that staff can manage BP
   - ☐ Other, please specify _____

   If no, has your site reviewed the possibility of the patient returning to BP active status?

   - ☐ No
   - ☐ Yes and participant remains in BP inactive status

## Part B. Visit Type

2. Was study data collected for this visit?

0 ☐ No (Skip to Part D below)

1 ☐ Yes

If yes, what type of contact is this?

1 ☐ Clinic

2 ☐ Home

3 ☐ Phone

5 ☐ Other (Please specify): _____

3. Is this contact for a visit specified in the protocol?

0 ☐ No (PRN visit)

1 ☐ Yes (Skip remaining questions in this section and complete Part C below)

Note: Protocol specified visits are Baseline, 1M, 2M, 3M and Q3 thereafter

4. Who initiated this PRN contact?

1 ☐ Participant

2 ☐ Clinic

3 ☐ Other (Please specify - e.g., PCP for BP check) _____

5. What was the reason for this PRN contact (Mark all that apply, then STOP)?

☐ Treatment/medication adjustment

☐ BP check OR follow-up after med change

☐ Draw safety labs OR follow-up on lab abnormality

☐ Adverse experience/symptoms (complete SAE FORM, if needed)

☐ Other (Please specify) _____

## Part C. Protocol-Specified Visit

6. Is this an annual visit?

0 ☐ No (Skip to Question 7)

1 ☐ Yes

If Yes, Was the My Health Form completed?

0 ☐ No (Skip to Question 7)

1 ☐ Yes

If Yes, Was the response to PHQ-9 Question 9, "more than half the days" or "nearly every day"?

0 ☐ No (Skip to Question 7)

1 ☐ Yes

If Yes, Did the PI or a designated site clinician assess the participant for risk of suicide before the participant left the clinic?

0 ☐ No (Skip to Question 7)

1 ☐ Yes

7. Was this a 24M or 48M visit?

0 ☐ No

1 ☐ Yes (Skip to Question 8)

**IF NO**, were MIND Screening or MIND Extended Battery forms included in the packet for this visit?

0 ☐ No (Skip to Question 8)

1 ☐ Yes

If yes, were the MIND tests completed?

0 ☐ No (complete MIND Cover Page only)

1 ☐ Yes (complete MIND Cover Page and data enter completed forms)

8. Was this protocol visit completed as specified in protocol?

- ☐ No (Note: Only count MIND as incomplete at the initial scheduled protocol visit: 24M or 48M visit)
- ☐ Yes (STOP HERE)

If no, indicate below the forms/data that were scheduled to be collected but are MISSING (Mark all that apply):

**Q3 FORMS**

- ☐ Events Ascertainment Form
- ☐ Blood Pressure Management Form
- ☐ Blood Pressure Medication Log
- ☐ Participant Contact Information Form

**Q6 FORMS; ALL OF THE ABOVE PLUS**

- ☐ Lab Shipment Form

**Q12 FORMS; ALL OF THE ABOVE PLUS**

- ☐ Annual History and Physical Exam Form
- ☐ My Health Form
- ☐ Men's/Women's Health Form (if form prints)
- ☐ Falls Self Efficacy Form (if form prints)
- ☐ Self-Administered Morisky Medications Adherence Scale

**Q24 FORMS; ALL OF THE ABOVE PLUS**

- ☐ MIND Screening Battery (if missing, MIND Cover Page should still be completed)
- ☐ For 2800 Participants only: MIND Extended Battery (if missing, MIND Cover Page should still be completed)
- ☐ ECG Form

If ECG **NOT** performed, specify why below:

_____

## Part D. Missed Visits

9. Indicate below the reason the visit was missed:

1 ☐ Participant cannot be located

2 ☐ Participant located but unable to make contact or collect data

3 ☐ Participant is hospitalized (Document in source notes when, where, and why participant was admitted. Complete an SAE FORM, if appropriate, and gather materials for event adjudication.

4 ☐ Participant died (Complete an SAE FORM)

5 ☐ Scheduling conflict

6 ☐ Participant is BP inactive for study treatment/Alternative follow-up plan has been established

7 ☐ Participant withdrew consent (Complete PARTICIPANT STATUS LOG)

8 ☐ Other (Please specify) _____

# SPRINT FSE

| | | | |
|---|---|---|---|
| Participant ID: | ___ ___ ___ ___ ___ ___ ___ ___ | Date of Visit: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| Visit: ASK | Site: ___ ___ ___ | Form Completed by: | __ __ __ __ |
| | | Date Entered: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| | | Data Entered by: | __ __ __ __ |

We would like to ask some questions about how concerned you are about the possibility of falling. Please reply thinking about how you usually do the activity. If you currently do not do the activity, please answer to show whether you think you would be concerned about falling IF you did the activity. For each of the following activities, please mark the box which is closest to your own opinion to show how concerned you are that you might fall if you did this activity.

| | | 1<br>Not at all concerned | 2<br>Somewhat concerned | 3<br>Fairly concerned | 4<br>Very concerned |
|---|---|---|---|---|---|
| 1 | Getting dressed or undressed | ☐ | ☐ | ☐ | ☐ |
| 2 | Taking a bath or shower | ☐ | ☐ | ☐ | ☐ |
| 3 | Getting in or out of a chair | ☐ | ☐ | ☐ | ☐ |
| 4 | Going up or down stairs | ☐ | ☐ | ☐ | ☐ |
| 5 | Reaching for something above your head or on the ground | ☐ | ☐ | ☐ | ☐ |
| 6 | Walking up or down a slope | ☐ | ☐ | ☐ | ☐ |
| 7 | Going out to a social event (e.g. religious service, family gathering or club meeting) | ☐ | ☐ | ☐ | ☐ |

# SPRINT - Inclusion/Exclusion Summary Form

Participant ID: ___ ___ ___ ___ ___ ___ ___ ___

Visit Code: 12M

Site: ___ ___ ___

Date of Visit: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

Form Completed by: __ __ __ __

Date Entered: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

Data Entered by: __ __ __ __

**Part A. Demographics (Please complete Part A for all participants screened in the clinic.)**

1. Participant Name:

   First: _____ Last: _____

2. Please tell us how you heard about the SPRINT study. Check all that apply.

   - ☐ A friend or relative
   - ☐ On the radio
   - ☐ On the television
   - ☐ In the newspaper
   - ☐ A brochure
   - ☐ A poster or a flier
   - ☐ Information that was mailed to you
   - ☐ You found it on the internet
   - ☐ You called an 800 number for information
   - ☐ Referral from your healthcare provider
   - ☐ SPRINT study staff mentioned it
   - ☐ Other (Specify) _____

3. Participant Gender ☐ Female ☐ Male

4. Is participant of Spanish, Hispanic or Latino origin?

   - ☐ No
   - ☐ Yes, Puerto Rican
   - ☐ Yes, Cuban
   - ☐ Yes, Mexican, Mexican American, Chicano
   - ☐ Yes, other Spanish/Hispanic/Latino Specify: _____

5. What is participant's race/ethnicity?

   - ☐ White, Caucasian
   - ☐ Black, African American
   - ☐ American Indian/Alaska Native
   - ☐ Native Hawaiian/Pacific Islander
   - ☐ Asian
   - ☐ Other Specify: _____

6. Participant Date of Birth __ __ / __ __ / 19 __ __ (mm/dd/yyyy)

   Is the participant ≥ 50 years of age?

   - ☐ No, participant is currently ineligible; **STOP HERE**
   - ☐ Yes

| **Part B. Blood Pressure & Antihypertensive Medication Use** | **Source Documentation Notes (not for data entry)** |
|---|---|

7. Current BP Medications

7a. ☐ Check here if participant is not taking BP medications, otherwise, complete information below:

| | Drug Name | Dose | Units |
|---|---|---|---|
| 1. | | | |
| 2. | | | |
| 3. | | | |
| 4. | | | |
| 5. | | | |

8. Blood Pressure

8a. Arm circumference __ __ cm

Check appropriate cuff size

☐ Arm > 50 cm (participant is ineligible; **STOP HERE**)

☐ Small (< 22 cm) ☐ Medium (22-32 cm)

☐ Large (32-42 cm) ☐ Extra Large (42-50 cm)

8b. Sitting Pressures

| | Systolic | Diastolic | Heart Rate |
|---|---|---|---|
| 1st | ____ mm Hg | ____ mm Hg | ____ bpm |
| 2nd | ____ mm Hg | ____ mm Hg | ____ bpm |
| 3rd | ____ mm Hg | ____ mm Hg | ____ bpm |
| Average | ____ mm Hg | ____ mm Hg | ____ bpm |

8c. Standing Pressures (taken one minute after standing)

☐ Check here if participant is unable to stand

| Systolic | Diastolic | Heart Rate |
|---|---|---|
| ____ mm Hg | ____ mm Hg | ____ bpm |

If Standing SBP < 110 mm Hg, participant is ineligible; Finish completing questions 8 and 9 and then **STOP**

8d. Is SBP 130 - 180 mm Hg inclusive on 0-1 BP medication, or
SBP 130 - 170 mm Hg inclusive on 2 BP medications, or
SBP 130 - 160 mm Hg inclusive on 3 BP medications, or
SBP 130 - 150 mm Hg inclusive on 4 BP medications?

☐ No, participant is currently ineligible

☐ Yes

9a. Is participant on 0 BP medications?

☐ No

☐ Yes

If Yes, is a prior SBP > 130 mm Hg documented?

☐ No, participant is currently ineligible. Schedule a second screening if participant is otherwise eligible.

☐ Yes (provide details below):

Date of prior SBP: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

Prior SBP value: ____ mm Hg

Source of previous SBP:

☐ Chart

☐ Screening Visit

(Answer only if participant is ineligible)

9b. Do you intend to modify therapy and rescreen this potential participant?

☐ No

☐ Yes

| **Part C. Cardiovascular Disease History & Risk Factors** | | | **Source Documentation Notes (not for data entry)** |
|---|---|---|---|
| 10. CVD History | | | |
| a. Myocardial Infarction | ☐ No | ☐ Yes | |
| b. Acute Coronary Syndrome with or without resting ECG changes, ECG changes on graded exercise test, or positive cardiac imaging study | ☐ No | ☐ Yes | |
| c. Coronary Revascularization (CABG, PCI) | ☐ No | ☐ Yes | |
| d. Carotid Endarterectomy or Carotid Stenting | ☐ No | ☐ Yes | |
| e. PAD with revascularization | ☐ No | ☐ Yes | |
| 11. Other clinical or subclinical CVD (within past 2 years) | | | |
| a. ≥ 50% stenosis of a coronary, carotid or lower extremity artery | ☐ No | ☐ Yes | |
| b. AAA ≥ 5 cm with or without repair | ☐ No | ☐ Yes | |
| c. Coronary Artery Calcium score ≥ 400 Agatston units | ☐ No | ☐ Yes | |
| d. Low ABI (≤ 0.90) | ☐ No | ☐ Yes | |
| e. LVH by computer ECG reading, Echogram report, or other Cardiac imaging procedure | ☐ No | ☐ Yes | |
| 12. Labs | | | |
| Serum Creatinine ____ mg/dl (within past 6 months) | | | |
| Total Cholesterol ____ mg/dl (within past 12 months) | | | |
| HDL ____ mg/dl (within past 12 months) | | | |

| | |
|---|---|
| 13. Current cigarette smoker?<br>☐ No<br>☐ Yes | |
| 14. Estimated GFR (within past 6 months)<br>14a. Enter value _____ ml/min/1.73m2<br>14b. Is eGFR ≥ 20 ml/min/1.73m2 ?<br>☐ No, participant is ineligible; **STOP HERE**<br>☐ Yes<br>14c. Is eGFR < 60 ml/min/1.73m2 ?<br>☐ No<br>☐ Yes | |
| 15. Framingham Risk Score<br>15a. Enter point total from SPRINT Look Up Table, including points for use of BP meds, smoking and ethnicity where appropriate<br>____ CVD points<br>15b. Is point total ≥ 13 for men or ≥ 16 for women?<br>☐ No<br>☐ Yes | Framingham Risk Scoring<br>Base Points _____<br>Smoking Points _____<br>Meds Points _____<br>Ethnicity Points _____<br>_____<br>Total Points _____ |
| 16. Are any of the responses to question 10, question 11, question 14c, or question 15b positive or is participant at least 75 years old?<br>☐ No, participant is ineligible; **STOP HERE**<br>☐ Yes | |
| **Part D. General Exclusion Criteria: You may stop screening if the response to any item is "YES".** | **Source Documentation Notes (not for data entry)** |
| 17. Known secondary cause of Hypertension that causes concern regarding safety of the protocol? ☐ No ☐ Yes | |
| 18. Unacceptable level of proteinuria within past 6 months? (See MOP for specifics) ☐ No ☐ Yes | |
| 19. Does the participant have diabetes? (see MOP for specifics) ☐ No ☐ Yes | |
| 20. History of stroke? ☐ No ☐ Yes | |
| 21. ESRD or Polycystic Kidney Disease? ☐ No ☐ Yes | |
| 22. Glomerulonephritis treated with Immunosuppressive therapy? ☐ No ☐ Yes | |

| | | |
|---|---|---|
| 23. Symptomatic HF within last 6 months or LV ejection fraction < 35%? | ☐ No ☐ Yes | |
| 24. Any medical condition likely to limit survival to less than 3 years? | ☐ No ☐ Yes | |
| 25. A cancer diagnosed and treated within the last 2 years that would compromise participant's ability to comply with protocol and complete trial? | ☐ No ☐ Yes | |
| 26. Living in same household as a randomized SPRINT participant? | ☐ No ☐ Yes | |
| 27. Any organ transplant. | ☐ No ☐ Yes | |
| 28. Indication for any specific BP med not currently taking without documented intolerance? | ☐ No ☐ Yes | |
| 29. Cardiovascular event, procedure or hospitalization for unstable angina within last 3 months? | ☐ No ☐ Yes | |
| 30. Any factors likely to limit adherence to intervention (see MOP for examples) ? | ☐ No ☐ Yes | |
| 31. Is participant currently participating in another clinical trial? | ☐ No ☐ Yes | |
| 32. Unintentional weight loss > 10% in last 6 months? | ☐ No ☐ Yes | |
| 33. Pregnant, trying to become pregnant, or of child-bearing potential and not practicing birth control? | ☐ No ☐ Yes | |
| **Part E. Informed Consent** | | |
| 34. Has the participant signed an informed consent to participate in SPRINT? | ☐ No ☐ Yes | |

**Part F. Contact Information**

35. Participant Address:

Street Address: _____

City: _____ State: __ __ Zip: __ __ __ __ __

36. Participant Phone Number:

Home: __ __ __ - __ __ __ - __ __ __ __ Work: __ __ __ - __ __ __ - __ __ __ __

Cell: __ __ __ - __ __ __ - __ __ __ __ Fax: __ __ __ - __ __ __ - __ __ __ __

37. Participant Email: _____

# Instructions for Inclusion/Exclusion Version 3

Note: There are some highlighted sections on the form; these are for clinic notes and source documentation but do not require data entry. These fields state “Source Documentation Notes- (not for data entry”).

Items 1 through 6 in Part A of this form should be completed and data entered for all prospective participants who come to the clinic for screening. You may wish to use this form as your documentation for all patients screened (including chart reviews and telephone calls). If at any point during the screening process the prospective participant is deemed ineligible, document the primary reason for ineligibility and stop form completion.

For eligible patients, please complete all parts of the form. Note that some individual items in Parts C and D may be marked 'no' and noted as 'not available' for eligible participants in the Source Documentation Notes area if no documented evidence of those individual items can be found.

Please note questions 35 – 37 at the end of the form. Collect participant contact information (address, phone numbers and email address). It is recommended that you collect this information for ineligible as well as eligible participants in case the participant can be contacted and re-screened at a later date.

**LINE BY LINE INSTRUCTIONS**

The participant ID label should be pre-printed on the form. Record the date of the visit using the mm/dd/yyyy format. . Record the SPRINT user ID on the space provided beside “Form Completed by.” The “Data Entered By” and “Date Entered” fields are not required, but may be used by clinics that wish to document data entry status on the form.

**Part A. Demographics**

1. Participant Name
Print the prospective participant’s full name in the appropriate boxes (first name and last name).

2. Please tell us how you heard about the SPRINT study. Check all that apply.

3. Participant Gender – Record the prospective participant’s gender.

4. Is this participant of Spanish, Hispanic or Latino origin? – This question asks how the participant would describe himself or herself. Ask the participant directly, using language with which you are comfortable, and that the participant will comprehend. If the participant responds ‘Yes’, ask him/her to specify the type of Hispanic group that best describes his/her heritage and mark that selection (Puerto Rican, Cuban, Mexican, Mexican American, Chicano, other). If other Spanish/Hispanic/Latino, please specify in the provided space.

5. What is the participant’s race/ethnicity? This question asks how the participant would describe himself or herself. Ask the participant directly, using language with which you are comfortable, and that the participant will comprehend. Pre-defined choices include: White, Caucasian; Black, African American; American Indian/Alaska Native; Native Hawaiian/Pacific Islander; Asian: Other. If other is selected, please specify in the provided space. Respondents may specify more than one race/ethnicity.

6. Participant Age: – Record the prospective participant's date of birth.

Indicate in the shaded area whether the prospective participant’s age is = 50. If participant is not > 50 years of age, they are INELIGIBLE at this time and may be re-screened at a later date when they are > 50 years of age.

**Part B. Blood Pressure & Antihypertensive Medication Use**

7. Current BP Medications

All blood pressure and antihypertensive medications prescribed at the time of the screening visit (i.e., the current pre-study antihypertensive medications) should be documented on the form. There is a check box to indicate that the participant is not taking any BP medications. Otherwise, complete a separate line for each medication in the following manner:

(a) Record the name of the medication in the “*Drug Name*” field. You may use either the generic or trade name.
(b) In the “*Dose*” column, record the prescribed dosage per day.
(c) In the “*Units”* column, record the prescribed units per day .

**8. Blood Pressure**

8a. Arm circumference in centimeters.
Measure the participant’s arm circumference with a tape measure and enter the number of centimeters (See MOP Chapter 3

for directions on cuff size determination). Note that an arm circumference of > 50cm makes the participant ineligible and ends data collection for this form. Otherwise, check the appropriate cuff size: Small (17- <22 cm), Medium (>22-<32 cm), Large (>32-<42 cm), Extra Large (>42-<50 cm).

8b. Enter sitting blood pressure and heart rate measurements.

Systolic BP (average of 3) mm Hg: Record the calculated average of the 3 systolic blood pressure readings from the Omron device in the space provided. Use leading zeros where appropriate.

Diastolic BP (average of 3) mm Hg: Record the calculated average of the 3 diastolic blood pressure readings from the Omron device in the space provided. Use leading zeros where appropriate.

Heart Rate (average of 3) bpm: Record the calculated average of the 3 heart rate determinations from the Omron device in the space provided. Use leading zeros where appropriate.

8c. Record the one standing blood pressure that is taken one minute after standing up from the sitting blood pressures. Enter the systolic BP mm Hg, diastolic BP mm Hg and heart rate bpm. Use leading zeros where appropriate. If the standing blood pressure is <110 mm Hg, the participant is INELIGIBLE and data collection ends for this form. The criterion is influenced by a consideration of the potential for orthostasis. Orthostasis in a participant with a history of standing BP< 110 mm Hg may pose a safety risk.

There is a check box to indicate if the participant is unable to stand (wheelchair, amputation without prosthesis, etc).

8d. Is SBP 130 – 180 mm Hg inclusive on 0-1 BP medication, or
SBP 130 – 170 mm Hg inclusive on 2 BP medications, or
SBP 130 – 160 mm Hg inclusive on 3 BP medications, or
SBP 130 – 150 mm Hg inclusive on 4 BP medications

Determine the number of blood pressure medications the participant is taking from question 7.

If the participant is currently taking 5 or more agents, then he/she is INELIGIBLE at this time. This can be recorded in the shaded area of the form.

If the participant is currently taking 4 agents, verify that the average of three of his/her SBP (question 8b) is between 130 and 150 mm Hg, inclusive. If so, mark 'yes,' Otherwise mark 'no' (the participant is INELIGIBLE).

If the participant is currently taking 3 agents, verify that the average of three of his/her SBP (question 8b) is between 130 and 160 mm Hg, inclusive. If so, mark 'yes,' otherwise mark 'no' (the participant is INELIGIBLE).

If the participant is currently taking 2 agents, verify that the average of three of his/her SBP (question 8b) is between 130 and 170 mm Hg, inclusive. If so, mark 'yes,' otherwise mark 'no' (the participant is INELIGIBLE).

If the participant is currently taking 0 -1 agent, verify that the average of three of his/her SBP (question 8b) is between 130 and 180 mm Hg, inclusive. If so, mark 'yes,' otherwise mark 'no' (the participant is INELIGIBLE).

9. Is participant on 0 BP medications?

If the participant is currently taking no anti-hypertensive agents, then there must be two documented SBPs > =130 mm Hg, with the second SBP < 180 mm Hg. Verify that there is a prior SBP value that is >130 mm Hg from either the participant's chart (measured within the last 3 months), or an SBP measurement taken at an SPRINT screening visit measured at least 1 day prior to the current visit.

If the participant is taking one or more BP medications "No." If the participant is taking no BP medications and has a measured SBP from this visit that is >130, mark "Yes" and continue.

If Yes, is a prior SBP >130 mm Hg documented? Determine whether there is a prior screening SBP measurement >130 mm Hg and within the specified time frame. If not, mark "No" and schedule a second screening visit if the participant is otherwise eligible. If there is a prior SBP >130, mark 'Yes' and provide the following details:

Date of prior SBP: Complete the date of the prior screening SBP. A SBP measurement from the participant's chart must have been recorded within three months of the current visit.

SBP Value: Indicate the value of the prior screening SBP mm Hg.

SBP Source: Indicate the source of the prior screening SBP in the Source Documentation Notes. This shaded field is not data-entered.

**Part C. Cardiovascular Disease History & Risk Factors**

**10. CVD History:** Check ‘Yes’ next to each cardiovascular event the participant has ever experienced (regardless of when it occurred). For each item marked 'Yes', supportive evidence of the diagnosis should be kept in the participant's chart. Note: participants with a CVD event within the last three months will be ineligible, but may be rescreened later. In these cases, mark ‘Yes’ next to the appropriate event here, then answer ‘Yes’ to Question 29.

**10a. Myocardial infarction** - Documentation of an old or age-indeterminate myocardial infarction (MI), may be by one of the following: Q-waves on an ECG; akinesis or dyskinesis on echocardiogram, MUGA, or ventriculogram; prior hospital discharge diagnosis, significant cardiac enzyme test results. If enzyme tests for this particular MI were performed on more than one date, please document the date of the total CPK, CK-MB, or Troponin-I that first became significant for occurrence of an MI, or verification from the primary or consulting physician that a MI has occurred. The date and location of the most recent MI may be listed in the source documentation area. After obtaining information, mark the appropriate box (Yes or No).

**10b. Acute coronary syndrome with or without resting ECG changes, ECG changes on Graded Exercise Test or positive cardiac imaging study** - Documentation of acute coronary syndrome and/or ischemic changes may be identified with the noninvasive cardiac diagnostic procedures such as exercise testing (ST depression = 1mm for =1 minute); stress echocardiography (reversible wall motion abnormality); and stress thallium (reversible or fixed ischemia, or SPECT). Place a copy of the report in the participant’s chart, and mark the appropriate box (Yes or No).

**10c. Coronary revascularization**: CABG; PCI) - Identification of the specific type of coronary revascularization should be listed in the source documents with supportive evidence filed in the participant’s chart. Some examples would be coronary artery bypass graft (CABG) surgery, stent placement, percutaneous transluminal coronary angioplasty (PTCA), rotoablation, or laser (LEAD) atherectomy. After obtaining information, mark the appropriate box (Yes or No), noting that CABG should be indicated separately from other types of coronary revascularizations.

**10d. Carotid Endarterectomy or Carotid Stenting**: carotid endarterectomy or stenting

**10e. PAD with Revascularization - p**eripheral artery revascularization: peripheral artery bypass, LEAD (leg) atherectomy or revascularization of other peripheral artery.

**11. Other clinical or subclinical CVD (within past 2 years).** A positive or negative history of each condition should be indicated (Yes or No) on the form. The date and location of each procedure should be listed in the source documentation. Copies of the associated hospital discharge summary procedure report(s) should be kept in the participant’s chart. After obtaining information, mark the appropriate box ('Yes' or 'No').

**11a. > 50% stenosis of a coronary, carotid or lower extremity artery:** This would be documented by traditional angiography, MR angiography, CT angiography, or Doppler ultrasound, with the date and type of angiogram or Doppler ultrasound and result listed in the source documents. A copy of the procedure report should be retained in the chart. After obtaining information, mark the appropriate box ('Yes' or 'No').

**11b. Abdominal Aortic Anerursm (AAA) > 5cm with or without repair**: AAA size would be assessed via ultrasound or AAA surgical repair with an operative report. The date and applicable procedure should be listed in the source documents. A copy of the procedure report should be retained as source documentation. After obtaining information, mark the appropriate box ('Yes' or 'No').

**11c. Coronary Artery Calcium score > 400 Agatston units:** The purpose of a calcium score is to determine if a patient is at high risk for coronary artery disease. In general, a high calcium score is associated with a higher risk of cardiovascular events. A calcium score looks specifically at calcium in the coronary arteries, where increased calcium is associated with narrowing of the artery. The calcium score is calculated from Computed Tomography (CT) scan images. The two main types of CT scanners are "Electron Beam" (EBCT) and "Multi-Detector" (MDCT). Both types of scanners are generally effective in calculating a calcium score. A copy of the cardiac CT report documenting the calcium score should be retained as source documentation. After obtaining information, mark the appropriate box ('Yes' or 'No').

**11d. Low ABI (< 0.90):** This ratio is indicative of advanced arterial obstruction and is obtained using a Doppler and specific protocol. The measurements and date obtained should be listed in the source documents. Place a copy of the report in the participant’s chart. After obtaining information, mark the appropriate box ('Yes' or 'No').

**11e. LVH by computer ECG reading, Echogram report, or other Cardiac imaging procedure:** An ECG or echocardiogram used for this criterion must have been performed within the 2 years prior to screening and a copy of the qualifying report kept in the participant’s chart for verification. After obtaining information, mark the appropriate box ('Yes' or 'No').

LVH by ECG includes any one of the following:

R amplitude in V5 or V6 > 26 mm.
R amplitude in V5 or V6 plus S amplitude in V1 > 35mm.
R amplitude in aVL > 12 mm
R amplitude in Lead I > 15 mm
R amplitude in Leads II or III, or aVF > 20 mm

R amplitude in Lead I plus plus S amplitude in Lead II1 > 25mm
R amplitude in aVL plus S amplitude in V3 >28 mm for men or > 22 mm for women
Computerized ECG machine documented LVH

For visual LVH reading, QRS amplitudes are measured in the second to last complete normal beat of the lead. A computerized reading indicating “borderline” or possible” LVH should be measured for the above listed voltage criteria and verified/signed by the provider who provides the interpretation. LVH by echocardiogram includes a combined wall thickness of 25 mm or more, which refers to the posterior wall plus the interventricular septum.

After obtaining information, mark the appropriate box ('Yes' or 'No').

**12. Labs**

**Serum creatinine.** What is the patient’s most recent serum creatinine mg/dl (within the past 6 months)?

**Total cholesterol.** What is the patient’s most recent total cholesterol mg/dl (within the past 12 months)?
List the most recent total cholesterol result and date performed. Retain a copy of the report in the chart. If the patient is currently receiving lipid-lowering medication, be sure to document the therapy in the source documents. This is not necessary for screening but will be needed at baseline, if eligible for randomization. If there are 2 or more values available in the medical records, the most recent value takes precedence. If a value < 12 months old is not available, consider obtaining locally if the participant is not otherwise eligible for SPRINT.

**HDL.** What is the patient’s most recent HDL cholesterol mg/dl (within the past 12 months)?
List the most recent HDL result and date performed. File a copy of the qualifying result in the chart. If a value < 12 months old is not available, consider obtaining locally if the participant is not otherwise eligible for SPRINT.

**13. Current cigarette smoker?** If the patient is currently smoking cigarettes or has smoked in the past 30 days, the patient would meet this criterion. No other tobacco use qualifies. Document the patient's cigarette smoking history in the source documents. After obtaining information, mark the appropriate box ('Yes' or 'No').

**14. Estimated GFR (within the past 6 months)**

14a. Enter the value of the eGFR ml/min/1.73m2 based on the 4-variable Modification of Diet in Renal Disease (MDRD) equation

Is the estimated eGFR > 20 ml/min/1.73m2? Check yes or no box; If no, participant is INELIGIBLE and data collection stops here.

Is the estimated eGFR < 60 ml/min/1.73m2? Check yes or no box.

**15. Framingham Risk Score (FRS)**

Framingham risk scores are based upon total and HDL cholesterol values obtained within the prior 12 months, gender, race, age, smoking status, systolic blood pressure and number of BP lowering medications – See the Framingham Risk Score Look-up Tables. Each table is organized based on values of age, SBP, HDL and total cholesterol, and the number in each cell is the points obtained from the combination of those four variables (plus gender). Each cell is then color coded to indicate the participant is eligible for SPRINT (green) or may be eligible based on additional points for being on BP meds and/or a smoker (yellow, blue and red). Clear cells are not eligible.

15a. Using the Framingham Risk Score Look-up Tables, begin by finding the row that corresponds to the total cholesterol, then the sub-row that corresponds to the HDL-C, then the column that corresponds to age and finally the sub-column that corresponds to SBP. Note the point total (adjusted for race/ethnicity where indicated) and color of the appropriate cell and cross-reference with the table key to determine eligibility related to this criterion.

Enter the point totals for the CVD risks based on the FRS look-up table.

Is this point total > 13 for men or > 16 for women? Enter “Yes” or “No” response.

16. Are any of the responses to question 10a-e, question 11a-e, question 14c or question 15b positive, or is participant at least 75 years old? If no, the participant is INELIGIBLE.

**REGARDING ELIGIBILITY:**

The participant must be at least 50 years of age (Part A, item 6) to be eligible for trial. If participant is currently ineligible but will turn 50 before the end of recruitment, they may be rescreened at a later date.

2. The participant must satisfy all of the criteria in Part B to be eligible for the trial. If the participant is currently ineligible based on the combination BP medication number and sitting systolic BP, the participant may be rescreened after adjusting

BP medications as described in section 8c above.

3. The participant must have elevated CVD risk based on age > 75 years, a positive history of clinical or subclinical CVD (indicated by a yes response to at least one item in question 10a-e or 11a-e), chronic kidney disease (indicated by a yes response to question 14c) or a Framingham risk score that exceeds gender specific cutpoints (indicated by a yes response to question 15b) to be eligible for the trial. Any one of these criteria is sufficient to establish eligibility based on elevated CVD risk.

**Part D. General Exclusion Criteria: You may stop screening if the response to any item is "YES".**

The participant's history and physical must be verified to ensure that none of the following exclusion criteria are present. A pertinent negative history for the criteria must be documented to confirm exclusion. If any of the following are present, the participant is not eligible for SPRINT. **Applicable inclusion & exclusion criteria should be carefully evaluated and clearly documented in the source documentation of the participant's study chart**.

If any of the following are present, the patient is **not** eligible for SPRINT. Check 'Yes' or 'No' for each question. If 'Yes' is checked, then the participant is not eligible to enroll in the study.

**Does this participant have any of the following:**

17. **Known secondary cause of hypertension** that causes concern regarding safety of the protocol? If yes, then participant is ineligible. Secondary causes of hypertension include obstructive sleep apnea, primary hyperaldosteronism, renal artery stenosis, renal parenchymal disease , excess catecholamines, coarctation of the aorta, Cushing's syndrome, pheochromocytoma, some drugs (e.g. sympathomimetic agents), diet (excess sodium intake), excess erythropoietin and some endocrine disorders (e.g. hyperthyroidism). Participants with uncontrolled or untreated conditions listed should be excluded. If hyperparathyroidism, which is known to be associated with hypertension, is treated or controlled, then there may be no concern and it is an issue of investigator judgment as to exclusion of the participant

18. **Unacceptable level of proteinuria** within past 6 months?
If yes then participant is INELIGIBLE. If no information is available within the last 6 months a measure of protein excretion must be obtained during the screening process to rule out the presence of proteinuria. Every SPRINT participant MUST be documented during screening to have urinary protein excretion less than 1 gram per day or the equivalent as specified in the protocol.
Proteinuria in the following ranges (based on a measurement within the past 6 months) excludes the participant:

a. 24 hour urinary protein excretion > 1 g/day, or

b. If measurement (a) is not available, then 24 hour urinary albumin excretion > 600 mg/day, or

c. If measurements (a) and (b) are not available, then spot urine protein/creatinine ratio > 1 g/g creatinine, or

d. If measurements (a), (b), and (c) are not available, then spot urine albumin/creatinine ratio > 600 mg/g creatinine, or

e. If measurements (a), (b), (c), and (d) are not available, then urine dipstick 2+ protein

When two or more results (of the same level in the proteinuria hierarchy listed above) within the past 6 months are available to the investigator, then the eligibility status is based on the majority result, that is, if the majority of results within the past 6 months for that measurement support inclusion, then include; otherwise exclude. Alternatively, investigators may choose to obtain a higher ranked measure in the hierarchy if in doubt regarding eligibility.

The protein dipstick grading table below can assist you with interpreting dipstick values to help make eligibility assessments in the absence of the hierarchical urine protein measures outlined above. Designations of 2+ or higher or concentrations greater than 100 mg/dL make the participant ineligible.

| Designation | Approximate Concentration |
|---|---|
| Trace | 15 mg/dL |
| 1+ | 30 mg/dL |
| 2+ | 100 mg/dL |
| 3+ | 300 mg/dL |
| 4+ | > 2000 mg/dL |

If no information is available within the last 6 months a measure of protein excretion must be obtained during the screening process to rule out the presence of proteinuria. After obtaining information, mark the appropriate box (Yes or No).

**19. Does the participant have diabetes mellitus?** In SPRINT diabetes mellitus is determined as follows: Participants taking medications for the treatment of diabetes at any time in the last 12 months are excluded. Participants are also excluded if there is documentation of: FPG at or above 126 mg/dL, A1C =6.5 percent, a two-hour value in an OGTT (2-h PG) at or above 200 mg/dL, or a random plasma glucose concentration =200 mg/dL. The diagnosis of diabetes must be confirmed on a subsequent day by repeat measurement, repeating the same test for confirmation. However, if two different tests (e.g., FPG and HbA1C) are available and are concordant for the diagnosis of diabetes, additional testing is not needed. If two different tests are discordant, the test that is diagnostic of diabetes should be repeated to confirm the diagnosis.

This means that people with a history of diabetes (based either on a prior diagnosis or use of diabetes medications within the past 12 months) are ineligible for the trial. In the absence of a history of diabetes, one or more HbA1c, FPG, two-hour OGTT, or random plasma glucose test within the past 12 months can be used to establish the presence or absence of diabetes. If all qualifying test results are negative, the participant is potentially eligible for the trial. If any of the qualifying tests are positive, the diagnosis should be confirmed by having the same test repeated on a different day. If the positive result is confirmed, the participant is ineligible for the trial. If sufficient evidence is not available from the medical record to establish the presence or absence of diabetes, an HbA1c, FPG, two-hour OGTT, or random plasma glucose test should be obtained during screening.

20. **History of Stroke**? If yes then patient is INELIGIBLE.
Determining eligibility when vague neurological symptoms potentially attributable to stroke are reported but there are non-definitive imaging results and/or a non-definitive diagnosis:

Clinical strokes are excluded. TIAs are not excluded. If there is no definitive diagnosis of stroke, it is up to the clinic PI to make a decision regarding eligibility. If the clinic PI is unable to make the decision, the next step is to seek advice at the CCN level. If a decision cannot be made at the CCN level, the RR&A Committee will review the case and make a determination of eligibility.

Determining eligibility when there is an old or age-indeterminate brain lesion consistent with a possible brain infarct on a brain imaging examination that was performed for a reason other than evaluation of stroke and there is no history of a stroke like syndrome:

Persons with a history of stroke are excluded. According to the protocol, “stroke is GENERALLY defined as neurological deficit of cerebrovascular cause that persists beyond 24 hours or is interrupted by death within 24 hours (World Health Organization, 1978 Cerebrovascular Disorders (Offset Publications). Geneva: World Health Organization. ISBN 9241700432.” Hence, an imaging test with a lesion consistent with a possible brain infarct in a person who does not have a history of a clinical scenario consistent with stroke does not meet the exclusion criterion, and such person can be included in SPRINT, if otherwise eligible.

21. **ESRD (defined as eGFR < 20 ml/min within the past 6 months) or Polycystic Kidney Disease?** If yes then patient is INELIGIBLE.

22. **Glomerulonephritis** treated with immunosuppressive therapy? If yes then patient is INELIGIBLE. There is not a general exclusion related to the use of immunosuppressives. Rheumatic disorders treated with immunosuppressive therapy are not excluded.

23. **Symptomatic Heart Failure within the past 6 months or left ventricular ejection fraction (by any method) <35%?** For those who have been asymptomatic for CHF within the past 6 months AND who have a recent EF above the cut-point, those individuals would be eligible. If yes then patient is INELIGIBLE. Question the participant and review the records to ensure that there are no symptoms or evidence of New York HA Class III or IV CHF, as listed below, at the time of enrollment.

**New York Heart Association CHF Classes:**
Class I – No limitations of physical activity, ordinary activity does not cause symptoms.
Class II – Slight limitation of physical activity, ordinary physical activity results in symptoms
Class III – Marked limitation of physical activity, comfortable at rest but less than ordinary physical activity causes symptoms
Class IV – Symptoms at rest

24. Any **medical condition likely to limit survival to less than 3 years**? If yes then patient is INELIGIBLE. Patients with life-threatening diseases would likely lead to non-cardiovascular deaths early in the study and therefore affect the power of the study to answer the study questions.

25. **Any malignancy** (non-melanoma skin cancer early stage prostate cancer, or localized breast cancer are examples of possible exceptions to this exclusion criterion and should be based upon the clinician’s assessment) within the last 2 years? If yes then patient is INELIGIBLE. Patients with life-threatening diseases would likely lead to non-cardiovascular deaths during the study and therefore affect the power of the study to answer the research questions.

26. **Living in same household as a randomized SPRINT participant**? Is a member of the participant's household currently enrolled in SPRINT? If yes then patient is INELIGIBLE. Living in the same household is defined as any cohabitation that includes a shared kitchen or eating arrangement. Having two participants from the same household randomized to different trial interventions could create difficulties with adherence.

27. A history of any **organ transplant?** If yes then patient is INELIGIBLE. Patients with organ transplants may be placed on multiple medications to suppress organ rejection, some of which may pose adverse interactions with the intervention.

28. **Indication for any specific BP med not currently taking without documented intolerance**? If yes then patient is INELIGIBLE. If the participant has a compelling indication for an evidence-based therapy with blood pressure lowering effects without any documented contraindication or intolerance to the therapy, the patient should be considered for initiation of that therapy and may be rescreened for eligibility following stabilization on the specified therapy.

29. **Cardiovascular event or procedure, or unstable angina within the last 3 months**? If yes then participant is INELIGIBLE . This would include MI and revascularization. A 3-month waiting period insures clinical stability before initiating more aggressive treatment. (NOTE: An angiogram, is a diagnostic test rather than an interventional procedure, and therefore, by itself, does not render a patient ineligible). If the answer is 'Yes', this participant may be re-screened after 3 months past the date of procedure or event if he/she meets all other criteria.

30. **Any factors likely to limit adherence to the trial interventions**? For example,

- Active alcohol or substance abuse within the last 12 months
- Plans to move outside the clinic catchment area in the next 2 years without the ability to transfer to another SPRINT site, or plans to be out of the study area for more than 3 months in the next year.
- Significant history of poor compliance with medications or attendance at clinic visits
- Significant concerns about participation in the study from spouse, significant other, or family members
- Lack of support from primary health care provider
- Residence too far from the study clinic site such that transportation is a barrier including persons who require transportation assistance provided by the SPRINT clinic funds for screening or randomization visits
- Residence in a nursing home. Persons residing in an assisted living or retirement community are eligible if they meet the other criteria.
- Clinical diagnosis of dementia, treatment with medications for dementia, or in the judgment of the clinician cognitively unable to follow the protocol
- Other medical, psychiatric, or behavioral factors that in the judgment of the Principal Investigator may interfere with study participation or the ability to follow the intervention protocol

If the patient has any of these issues, please check (yes) and exclude the patient. The importance of adherence to the protocol is crucial to the success of SPRINT. A patient with any of the factors listed above may be eligible by all other criteria and will sign a consent form but may also be likely to subsequently refuse to take the prescribed medications or attend clinic visits. It is in the best interest of the patients, as well as the study's, that you evaluate their long-term commitment to carrying out the protocol.

Support from the Primary Care Physician (PCP) can also be very important. Lack of support can be quite adverse to long-term retention and adherence. Encourage potential participants to have discussions with their PCPs prior to obtaining consent. Give participants adequate time to have these discussions, provide informational materials to assist in this process, and document the process in your source notes.

Communicate with the PCP early and often during the trial, in accordance with permissions provided by the participants. Primarily out of respect for participant autonomy, but also due to logistical concerns, we are not adopting a requirement for PCP explicit and documented approval prior to randomization; however, evidence of lack of support from the PCP should be considered by clinic staff and investigators when deciding whether to enroll a potentially eligible person during the screening process.

31. **Currently participating in another clinical trial?** If yes, the patient may or may not be eligible.
Patients cannot be enrolled into SPRINT if already participating in another interventional clinical trial.
Observational studies are acceptable. The screenee must wait until the completion of his or her activities in the other interventional clinical trial prior to the SPRINT randomization visit to participate in SPRINT.

32. **Unintentional weight loss > 10% in the last 6 months**? If yes, the participant is INELIGIBLE. This participant could conceivably be rescreened once participant's weight has stabilized if they meet all other criteria

33. **Pregnant or trying to get pregnant**, **or of child-bearing potential and not actively using birth control?** If yes the participant is ineligible due to concerns regarding the effectiveness and safety of the intervention in pregnancy..

**Part E. Informed Consent**

34. Has the participant signed the informed consent for the SPRINT trial? If no, then participant is ineligible. The informed consent MUST be signed prior to enrollment into the trial.

**Part F Contact Information**

35. Obtain and enter the participant’s address, city, state and zip code.

36. Obtain and record all participant phone numbers including home, cell, work and fax numbers.

37. Obtain and record the participant’s email address if available.

# SPRINT Intensive BP Management Form
## 1M Visit

| | | | |
|---|---|---|---|
| Participant Name: | _____ | Date of Visit: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| Participant ID: | ___ ___ ___ ___ ___ ___ ___ ___ | Form Completed by: | __ __ __ __ |
| Visit: ASK | Site: ___ ___ ___ | Date Entered: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| | | Data Entered by: | |

**Part A. Previous Blood Pressure ____/____ mm Hg at ____ M Visit on __ __/__ __/__ __**

**Part B. Current Blood Pressure (Cuff Size used at _____ was _____ )**

1. ☐ Check here if measurement was not performed using the study automated device.

Seated Measurements

| | Systolic | Diastolic | Heart Rate |
|---|---|---|---|
| 1st | _____ mmHg | _____ mmHg | _____ bpm |
| 2nd | _____ mmHg | _____ mmHg | _____ bpm |
| 3rd | _____ mmHg | _____ mmHg | _____ bpm |
| Average | _____ mmHg | _____ mmHg | _____ bpm |

2. ☐ Check here and SKIP to Part C if participant is unable to stand.

Standing Measurement (@ 1 minute)

| Systolic | Diastolic | Heart Rate |
|---|---|---|
| _____ mmHg | _____ mmHg | _____ bpm |

3. Did participant experience dizziness or light headed feelings when standing for this exam?

- ☐ No
- ☐ Yes

## Part C. Treatment Algorithm

4. Is the current seated SBP < 120 mm Hg?

- ☐ No
- ☐ Yes

If No, the protocol requires intensification of therapy (medication added or dose increased). Will therapy be intensified at this visit?

- ☐ No; Continue with question 5 below
- ☐ Yes; **STOP HERE and complete Medication Log**

If Yes, is the current seated DBP ≥ 100 mm Hg or is DBP ≥ 90 mm Hg for last two visits?

- ☐ No; **STOP HERE and complete Medication Log**
- ☐ Yes

If yes, the protocol requires intensification of therapy (medication added or dose increased). Will therapy be intensified at this visit?

- ☐ No; Continue with question 5 below
- ☐ Yes; **STOP HERE and complete Medication Log**

5. Specify reason(s) protocol mandated changes were not made.

- ☐ Addressed adherence problem
- ☐ Participant refusal
- ☐ In consultation with CCN, decision made not to alter therapy for this participant
- ☐ Other (specify: _____ )

# SPRINT Intensive BP Management Form
## 2M, 3M, 9M, 15M, 21M, 27M, 33M, 39M, 45M, 51M, 57M, 63M, 69M and PRN Visits

| | | | |
|---|---|---|---|
| Participant Name: | _____ | Date of Visit: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| Participant ID: | ___ ___ ___ ___ ___ ___ ___ ___ | Form Completed by: | __ __ __ __ |
| Visit: ASK | Site: ___ ___ ___ | Date Entered: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| | | Data Entered by: | __ __ __ __ |

**Part A. Previous Blood Pressure ____/____ mm Hg at ____ M Visit on __ __/__ __/__ __**

**Part B. Current Blood Pressure (Cuff Size used at _____ was _____ )**

1. ☐ Check here if measurement was not performed using the study automated device.

Seated Measurements

| | Systolic | Diastolic | Heart Rate |
|---|---|---|---|
| 1st | _____ mmHg | _____ mmHg | _____ bpm |
| 2nd | _____ mmHg | _____ mmHg | _____ bpm |
| 3rd | _____ mmHg | _____ mmHg | _____ bpm |
| Average | _____ mmHg | _____ mmHg | _____ bpm |

**Part C. Treatment Algorithm**

2. Is the current seated SBP < 120 mm Hg?

☐ No

☐ Yes

If No, the protocol requires intensification of therapy (medication added or dose increased). Will therapy be intensified at this visit?

☐ No; Continue with question 3

☐ Yes; **STOP HERE and complete Medication Log**

If Yes, is the current seated DBP ≥ 100 mm Hg or is DBP ≥ 90 mm Hg for last two visits?

☐ No; **STOP HERE and complete Medication Log**

☐ Yes

If yes, the protocol requires intensification of therapy (medication added or dose increased). Will therapy be intensified at this visit?

☐ No; Continue with question 3

☐ Yes; **STOP HERE and complete Medication Log**

3. Specify reason(s) protocol mandated changes were not made.
   - ☐ Addressed adherence problem
   - ☐ Participant refusal
   - ☐ In consultation with CCN, decision made not to alter therapy for this participant
   - ☐ Other (specify: _____ )

# SPRINT Intensive BP Management Form
# 6M, 12M, 24M, 36M, 48M, 60M and 72M Milepost Visits

| | | | |
|---|---|---|---|
| Participant Name: | _____ | Date of Visit: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| Participant ID: | ___ ___ ___ ___ ___ ___ ___ ___ | Form Completed by: | __ __ __ __ |
| Visit: ASK | Site: ___ ___ ___ | Date Entered: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| | | Data Entered by: | |

**Part A. Previous Blood Pressure ____/____ mm Hg at ____ M Visit on __ __/__ __/__ __**

**Part B. Current Blood Pressure (Cuff Size used at _____ was _____ )**

1. ☐ Check here if measurement was not performed using the study automated device.

Seated Measurements

| | Systolic | Diastolic | Heart Rate |
|---|---|---|---|
| 1st | _____ mmHg | _____ mmHg | _____ bpm |
| 2nd | _____ mmHg | _____ mmHg | _____ bpm |
| 3rd | _____ mmHg | _____ mmHg | _____ bpm |
| Average | _____ mmHg | _____ mmHg | _____ bpm |

2. ☐ Check here and SKIP to Part C if participant is unable to stand.

Standing Measurement (@ 1 minute)

| Systolic | Diastolic | Heart Rate |
|---|---|---|
| _____ mmHg | _____ mmHg | _____ bpm |

3. Did participant experience dizziness or light headed feelings when standing for this exam?

☐ No

☐ Yes

## Part C. Milepost Visit Treatment Algorithm

4. Is the current seated SBP < 120 mm Hg?

- ☐ No
- ☐ Yes

If No, protocol requires a medication be added at Milepost visits. Will a medication be added at this visit?

- ☐ No; Continue with question 5 below **and also complete a Milepost Exemption Form**
- ☐ Yes; **STOP HERE and complete Medication Log**

If Yes, is the current seated DBP ≥ 100 mm Hg or is DBP ≥ 90 mm Hg for last two visits?

- ☐ No; **STOP HERE and complete Medication Log**
- ☐ Yes

If yes, the protocol requires intensification of therapy (medication added or dose Increased). Will therapy be intensified at this visit?

- ☐ No; Continue with question 5 below
- ☐ Yes; **STOP HERE and complete Medication Log**

5. Specify reason(s) protocol mandated changes were not made.

- ☐ Addressed adherence problem
- ☐ Participant refusal
- ☐ In consultation with CCN, decision made not to alter therapy for this participant
- ☐ Other (specify: _____ )

**SPRINT Intensive BP Management Form**
**18M, 30M, 42M, 54M, and 66M Milepost Visits**

| | | | |
|---|---|---|---|
| Participant Name: | _____ | Date of Visit: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| Participant ID: | ___ ___ ___ ___ ___ ___ ___ ___ | Form Completed by: | __ __ __ __ |
| Visit: ASK | Site: ___ ___ ___ | Date Entered: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| | | Data Entered by: | |

**Part A. Previous Blood Pressure ____/____ mm Hg at ____ M Visit on __ __/__ __/__ __**

**Part B. Current Blood Pressure (Cuff Size used at _____ was _____ )**

1. ☐ Check here if measurement was not performed using the study automated device.

Seated Measurements

| | Systolic | Diastolic | Heart Rate |
|---|---|---|---|
| 1st | _____ mmHg | _____ mmHg | _____ bpm |
| 2nd | _____ mmHg | _____ mmHg | _____ bpm |
| 3rd | _____ mmHg | _____ mmHg | _____ bpm |
| Average | _____ mmHg | _____ mmHg | _____ bpm |

**Part C. Milepost Visit Treatment Algorithm**

2. Is the current seated SBP < 120 mm Hg?

☐ No

☐ Yes

If No, protocol requires a medication be added at Milepost visits. Will a medication be added at this visit?

☐ No; Continue with question 3 **and also complete a Milepost Exemption Form**

☐ Yes; **STOP HERE and complete Medication Log**

If Yes, is the current seated DBP ≥ 100 mm Hg or is DBP ≥ 90 mm Hg for last two visits?

☐ No; **STOP HERE and complete Medication Log**

☐ Yes

If yes, the protocol requires intensification of therapy (medication added or dose increased). Will therapy be intensified at this visit?

☐ No; Continue with question 3

☐ Yes; **STOP HERE and complete Medication Log**

3. Specify reason(s) protocol mandated changes were not made.
   - ☐ Addressed adherence problem
   - ☐ Participant refusal
   - ☐ In consultation with CCN, decision made not to alter therapy for this participant
   - ☐ Other (specify: _____ )

# SPRINT - MIND Extended Battery

| | | | |
|---|---|---|---|
| Participant Name: | _____ | Date of Visit: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| Participant ID: | ___ ___ ___ ___ ___ ___ ___ ___ | Form Completed by: | __ __ __ __ |
| Visit: ASK | Site: ___ ___ ___ | Date Entered: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| | | Data Entered by: | |

| Test Completed? | | | If not completed, check all reasons that apply... | | | |
|---|---|---|---|---|---|---|
| | No | Yes | Physical Reason | Participant Refused | Participant Unable to Understand | Other |
| HVLT-R | ☐ | ☐ | ☐ | ☐ | ☐ | |
| Trail Making Test A | ☐ | ☐ | ☐ | ☐ | ☐ | |
| Trail Making Test B | ☐ | ☐ | ☐ | ☐ | ☐ | |
| Boston Naming Test | ☐ | ☐ | ☐ | ☐ | ☐ | |
| Rey-O Copy | ☐ | ☐ | ☐ | ☐ | ☐ | |
| Rey-O Recall | ☐ | ☐ | ☐ | ☐ | ☐ | |
| Category Fluency Animals | ☐ | ☐ | ☐ | ☐ | ☐ | |
| Digit Span Forward | ☐ | ☐ | ☐ | ☐ | ☐ | |
| Digit Span Backward | ☐ | ☐ | ☐ | ☐ | ☐ | |
| HVLT-R Delayed | ☐ | ☐ | ☐ | ☐ | ☐ | |
| HVLT-R Recognition | ☐ | ☐ | ☐ | ☐ | ☐ | |

Is this a home visit? ☐ Yes ☐ No

Do you believe that any vision impairment interfered with the participant's performance on these tests?
☐ Yes ☐ No

Do you believe that any hearing impairment interfered with the participant's performance on these tests?
☐ Yes ☐ No

Additional Notes:

## TRAIL MAKING TESTS A & B

**Part A Instructions:** Place the Part A sample form in front of the participant. Read aloud the instructions.

Say: **"En esta página hay círculos con números dentro de los círculos. Por favor tome un lápiz y dibuje una línea que vaya conectando de un número al otro en orden. Comience con el número 1** (point to the number), **y siga hacia el número 2** (point to the number), **luego siga hacia el 3** (point to the number) **y así en adelante. Por favor trate de no levantar el lápiz del papel a medida hace la línea que va de un círculo hacia el próximo círculo. Hágalo lo más rápido que pueda. ¿Listo? Comience ya."**

If the participant makes an error, mark through the line and go back to the point at which the error was made and say, for example, **"Usted estaba en el número 2. ¿Cuál es el próximo número?"** Wait for the participant's response and say, **"Por favor comience aquí y siga."**

If the participant completes the sample correctly, go to Test A. Repeat the instructions given for the sample.

Say: **"En esta página hay círculos con números dentro de los círculos. Por favor tome un lápiz y dibuje una línea que vaya conectando de un número al otro en orden. Comience con el número 1** (point to the number), **y siga hacia el número 2** (point to the number), **luego siga hacia el 3** (point to the number) **ay así en adelante. Por favor trate de no levantar el lápiz del papel a medida hace la línea que va de un círculo hacia el próximo círculo. Hágalo lo más rápido que pueda. ¿Listo? Comience ya."** Start timing as soon as the instruction is given to begin.

- Stop timing when Trail is completed or stop participant when maximum time is reached.
- Allow 5 minutes (300 seconds) for the test. YOUR STOPWATCH SHOULD READ 5:00

**Scoring:**
**Part A time to complete: ____ : ____ ____ Part A number of errors: ____**

**Part B Instructions:** Place the Part B sample form in front of the participant. Read aloud the instructions.

Say: **"En esta página hay círculos con números y letras dentro de los círculos. Por favor tome un lápiz y dibuje una línea que vaya alternando entre números y letras en orden. Comience con el número 1** (point to the number), **luego siga hacia la primera letra, A** (point to the letter), **de ahí siga al siguiente número, 2** (point to the number) **de ahí siga hacia la siguiente letra, B** (point to the letter), **y así en adelante. Por favor trate de no levantar el lápiz del papel a medida hace la línea que va de un círculo hacia el próximo círculo. Hágalo lo más rápido que pueda.¿Listo? Comience ya."**

If the participant makes an error, mark through the line and go back to the point at which the error was made and say, for example, **"Usted estaba en el número 2. ¿Cuál es la próxima letra?"** Wait for the participant's response and say, **"Por favor comience aquí y siga."**

If the participant completes the sample correctly, go to Test B. Repeat the instructions given for the sample.

Say: **"En esta página hay círculos con números y letras dentro de los círculos. Por favor tome un lápiz y dibuje una línea que vaya alternando entre números y letras en orden. Comience con el número 1** (point to the number), **luego siga hacia la primera letra, A** (point to the letter), **tde ahí siga al siguiente número, 2** (point to the number) **de ahí siga hacia la siguiente letra, B** (point to the letter), **y así en adelante. Por favor trate de no levantar el lápiz del papel a medida hace la línea que va de un círculo hacia el próximo círculo. Hágalo lo más rápido que pueda. ¿Listo? Comience ya."** Start timing as soon as the instruction is given to begin.

- Stop timing when Trail is completed or stop participant when maximum time is reached.
- Allow 5 minutes (300 seconds) for the test. YOUR STOPWATCH SHOULD READ 5:00

**Scoring:**
**Part B time to complete: ____ : ____ ____ Part B number of errors: ____**

# BOSTON NAMING TEST

(Maximum time: 20 seconds per picture)

Say, ***"Ahora le voy a mostrar algunas fotos y quiero que me diga el nombre de lo que aparece en cada foto."***

- If the participant responds with the correct item name, mark as correct (1 point).
- Do not provide the cue if the participant's response is incorrect.
- Provide the cue only if the participant says "I don't know" or misperceives the picture (i.e. "snake" for "pretzel"). If the participant then responds with the correct item name, score as correct.
- A non-specific prompt can be used if the response is correct but too general. For example, if the response to the "dominoes" is "game", or the response for "acorn" is "nut", say **"Is there another name for that?"** You may NOT ask "Isn't that a special kind of game/nut?" If the specific name is not given, score as incorrect (0 points).
- Only 1 cue or prompt is allowed per item.

| Picture | Correct | Incorrect |
|---|---|---|
| **Pretzel** (comida; algo que se come) | ☐ | ☐ |
| **Caballito de Mar** (un animal del océano; de mar) | ☐ | ☐ |
| **Rinoceronte** (un animal) | ☐ | ☐ |
| **Bellota** (de un árbol; fruto) | ☐ | ☐ |
| **Domino** (un juego) | ☐ | ☐ |
| **Pelicano** (un pájaro) | ☐ | ☐ |
| **Estetoscopio** (lo usan doctores y enfermeras) | ☐ | ☐ |
| **Bozal** (se le pone a los perros) | ☐ | ☐ |
| **Unicornio** (un animal imaginario; mítico) | ☐ | ☐ |
| **Espárragos** (algo que comer) | ☐ | ☐ |
| **Pergamino ; Rollo** (un documento) | ☐ | ☐ |
| **Tenazas** (una herramienta; utensilio) | ☐ | ☐ |
| **Esfinge** (es egipcio; de Egipto) | ☐ | ☐ |
| **Enrejado** (se usa en los jardines) | ☐ | ☐ |
| **Paleta** (los usan los artistas; pintores) | ☐ | ☐ |

**Total Correct _____**

# SPRINT-MIND Rey-O Fax Cover Page

**Participant ID: ___ ___ ___ ___ ___ ___ ___ ___**

**Visit: ASK**

**Site: ___ ___ ___**

**Date: ___ ___ / ___ ___ / ___ ___ ___ ___**

**FAX TO:** NANCY WOOLARD, SPRINT-MIND CC

**FAX NUMER:** 336-713-8800

**FROM: _____**

**DATE: _____**

**CONTACT NUMBER: _____**

Rey-O Copy

# Rey-O Immediate Recall

# Category Fluency Test -- Animals

Say, ***"Le voy a nombrar una categoría de cosas y quiero que usted me nombre, lo más rápido que pueda, cosas que pertenezcan a esa categoría de cosas. Por ejemplo, si yo digo "artículos de vestir" usted me podría decir 'camisa,' 'corbata,' o 'sombrero'. ¿Puede usted decirme el nombre de otros artículo de vestir?"***

Allow the participant to produce 2 responses. If they are not articles of clothing, you can say, ***"No, X no es (son) un artículo de vestir. Usted podría haber dicho 'zapatos' o 'saco' ya que estos sí son artículos de vestir."***

Then, read the following instructions:

***"Ahora, quiero que me nombre cosas que pertenecen a otra categoría: Animales. Usted tendrá un minuto. Quiero que me nombre todos los animales que pueda recordar en un minuto. ¿Listo? Comience ya."***

Start the timer as you say "begin." One prompt ***("Dígame todos los animales que se le ocurran")*** is permitted if the participant makes no response for 15 seconds or expresses incapacity (e.g., "I can't think of any more"). Stop the participant at 60 seconds.

| | | | |
|---|---|---|---|
| 1 | | 16 | |
| 2 | | 17 | |
| 3 | | 18 | |
| 4 | | 19 | |
| 5 | | 20 | |
| 6 | | 21 | |
| 7 | | 22 | |
| 8 | | 23 | |
| 9 | | 24 | |
| 10 | | 25 | |
| 11 | | 26 | |
| 12 | | 27 | |
| 13 | | 28 | |
| 14 | | 29 | |
| 15 | | 30 | |

**TOTAL: _____**

# DIGIT SPAN - FORWARD

**Digit Span Forward Instructions:**

**Items 1-8**

To introduce the task, say, **Ahora yo voy a decir algunos números. Escuche con atención, los voy a decir una sola vez. Cuando yo termine de decir los números quiero que me los repita en el mismo orden que yo los dije. Solo repita lo mismo que yo digo.** Proceed to Trial 1 of Item 1.

Administer Trial 1 and Trial 2 of each item. Proceed to the next item if the discontinue criterion has not been met.

Remember to administer Backward regardless of the examinee's performance on Forward.

| Item | Trial | Correct | Incorrect |
|---|---|---|---|
| 1. | 9 - 7 | 1 | 0 |
| | 6 - 3 | 1 | 0 |
| 2. | 5 - 8 - 2 | 1 | 0 |
| | 6 - 9 - 4 | 1 | 0 |
| 3. | 7 - 2 - 8 - 6 | 1 | 0 |
| | 6 - 4 - 3 - 9 | 1 | 0 |
| 4. | 4 - 2 - 7 - 3 - 1 | 1 | 0 |
| | 7 - 5 - 8 - 3 - 6 | 1 | 0 |
| 5. | 3 - 9 - 2 - 4 - 8 - 7 | 1 | 0 |
| | 6 - 1 - 9 - 4 - 7 - 3 | 1 | 0 |
| 6. | 4 - 1 - 7 - 9 - 3 - 8 - 6 | 1 | 0 |
| | 6 - 9 - 1 - 7 - 4 - 2 - 8 | 1 | 0 |
| 7. | 3 - 8 - 2 - 9 - 6 - 1 - 7 - 4 | 1 | 0 |
| | 5 - 8 - 1 - 3 - 2 - 6 - 4 - 7 | 1 | 0 |
| 8. | 2 - 7 - 5 - 8 - 6 - 3 - 1 - 9 - 4 | 1 | 0 |
| | 7 - 1 - 3 - 9 - 4 - 2 - 5 - 6 - 8 | 1 | 0 |

Total Correct _____

# DIGIT SPAN - BACKWARD

**Digit Span Backward Instructions:**

**Sample Item**

Trial 1

Say, **Ahora voy a decir algunos números más, pero esta vez, cuando yo pare, quiero que me los repita al revés, o sea, en el orden inverso. Si yo digo 7 - 1, ¿qué diría usted?**

Correct response [1 - 7]: Say, **Correcto.** Proceed to Trial 2.

Incorrect response: Say, **La respuesta no es del todo correcta. Yo dije 7 - 1, y para decirlo al revés usted debería contestar 1 - 7.** Proceed to Trial 2.

Trial 2

Say, **Vamos a intentarlo de nuevo. Recuerde de decirlo al revés. 3 - 4.**

Correct response [4 - 3]: Say, **Correcto. Probemos otra vez.** Proceed to Trial 1 of Item 1.

Incorrect response: Say, **La respuesta no es del todo correcta. Yo dije 3 - 4, y para decirlo al revés usted debería contestar 4 - 3. Probemos otra vez.** Proceed to Trial 1 of Item 1.

Administer Trial 1 and Trial 2 of each item. Proceed to the next item if the discontinue criterion has not been met.

| Item | Trial | Correct Response | Correct | Incorrect |
|---|---|---|---|---|
| S. | 7 - 1 | 1 - 7 | | |
| | 3 - 4 | 4 - 3 | | |
| 1. | 3 - 1 | 1 - 3 | 1 | 0 |
| | 2 - 4 | 4 - 2 | 1 | 0 |
| 2. | 4 - 6 | 6 - 4 | 1 | 0 |
| | 5 - 7 | 7 - 5 | 1 | 0 |
| 3. | 6 - 2 - 9 | 9 - 2 - 6 | 1 | 0 |
| | 4 - 7 - 5 | 5 - 7 - 4 | 1 | 0 |
| 4. | 8 - 2 - 7 - 9 | 9 - 7 - 2 - 8 | 1 | 0 |
| | 4 - 9 - 6 - 8 | 8 - 6 - 9 - 4 | 1 | 0 |
| 5. | 6 - 5 - 8 - 4 - 3 | 3 - 4 - 8 - 5 - 6 | 1 | 0 |
| | 1 - 5 - 4 - 8 - 6 | 6 - 8 - 4 - 5 - 1 | 1 | 0 |
| 6. | 5 - 3 - 7 - 4 - 1 - 8 | 8 - 1 - 4 - 7 - 3 - 5 | 1 | 0 |
| | 7 - 2 - 4 - 8 - 5 - 6 | 6 - 5 - 8 - 4 - 2 - 7 | 1 | 0 |
| 7. | 8 - 1 - 4 - 9 - 3 - 6 - 2 | 2 - 6 - 3 - 9 - 4 - 1 - 8 | 1 | 0 |
| | 4 - 7 - 3 - 9 - 6 - 2 - 8 | 8 - 2 - 6 - 9 - 3 - 7 - 4 | 1 | 0 |
| 8. | 9 - 4 - 3 - 7 - 6 - 2 - 1 - 8 | 8 - 1 - 2 - 6 - 7 - 3 - 4 - 9 | 1 | 0 |
| | 7 - 2 - 8 - 1 - 5 - 6 - 4 - 3 | 3 - 4 - 6 - 5 - 1 - 8 - 2 - 7 | 1 | 0 |

Total Correct _____

# SPRINT - MIND Screening Battery

Participant Name: _____

Participant ID: ___ ___ ___ ___ ___ ___ ___ ___

Visit: ASK Site: ___ ___ ___

Date of Visit: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

Form Completed by: __ __ __ __

Date Entered: __ __ / __ __ / 20 __ __ (mm/dd/yyyy)

Data Entered by: __ __ __ __

| Test Completed? | | | If not completed, check all reasons that apply... | | | |
|---|---|---|---|---|---|---|
| | No | Yes | Physical Reason | Participant Refused | Participant Unable to Understand | Other |
| Logical Memory - Immediate Recall | ☐ | ☐ | ☐ | ☐ | ☐ | |
| Montreal Cognitive Assessment (MOCA) | ☐ | ☐ | ☐ | ☐ | ☐ | |
| Digit Symbol Coding (DSC) | ☐ | ☐ | ☐ | ☐ | ☐ | |
| Logical Memory - Delayed Recall | ☐ | ☐ | ☐ | ☐ | ☐ | |

Is this a home visit?

☐ Yes ☐ No

Do you believe that any vision impairment interfered with the participant's performance on these tests?

☐ Yes ☐ No

Do you believe that any hearing impairment interfered with the participant's performance on these tests?

☐ Yes ☐ No

Additional Notes:

# LOGICAL MEMORY - IMMEDIATE RECALL

## Immediate Recall

| Item | Detail | 1-Point Criteria | First Recall Score | | Second Recall Score | |
|---|---|---|---|---|---|---|
| 1. | Ruth | *Ruth* or Ruthie | 0 | 1 | 0 | 1 |
| 2. | and Paul | *Paul* or Paulie | 0 | 1 | 0 | 1 |
| 3. | have been friends | *friends* (in any context) | 0 | 1 | 0 | 1 |
| 4. | for thirty | *thirty* (in any context) is required | 0 | 1 | 0 | 1 |
| 5. | years. | *year(s)* is required | 0 | 1 | 0 | 1 |
| 6. | They meet | *meet* (any indication of intentionally getting together) | 0 | 1 | 0 | 1 |
| 7. | every | *every* (in reference to Tuesday only) or *on Tuesdays* | 0 | 1 | 0 | 1 |
| 8. | Tuesday | *Tuesday(s)* (in any context) is required | 0 | 1 | 0 | 1 |
| 9. | at Alma's | *Alma's* (in any context) is required | 0 | 1 | 0 | 1 |
| 10. | Diner | *Diner* is required | 0 | 1 | 0 | 1 |
| 11. | for breakfast | *breakfast* (in any context) is required | 0 | 1 | 0 | 1 |
| 12. | and then they go for a walk | indication that they walk (e.g. stroll) | 0 | 1 | 0 | 1 |
| 13. | in Mason | *Mason* (in any context) is required | 0 | 1 | 0 | 1 |
| 14. | Park. | *Park* (in any context) is required | 0 | 1 | 0 | 1 |

Use the space below to write the examinee's verbatim responses if needed.

**First Recall Total**
(maximum = 14) ☐

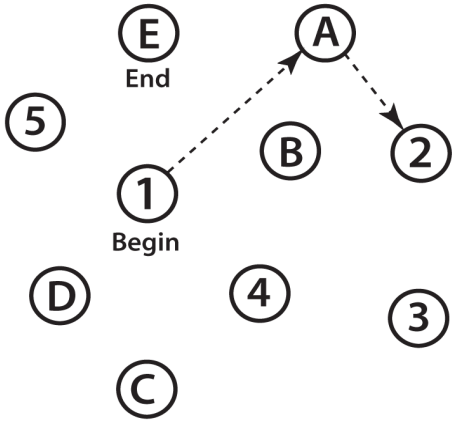
**Second Recall Total**
(maximum = 14) ☐

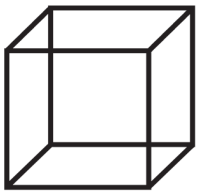
First Recall

Second Recall

# MONTREAL COGNITIVE ASSESSMENT (MOCA)

## VISUOSPATIAL / EXECUTIVE



Copy cube

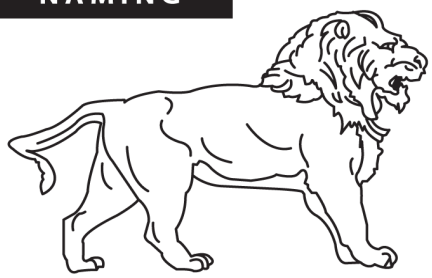
[ ] [ ]

Draw CLOCK (Ten past eleven)
( 3 points )

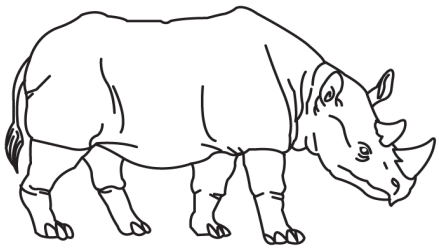
[ ] Contour [ ] Numbers [ ] Hands

POINTS ___/5

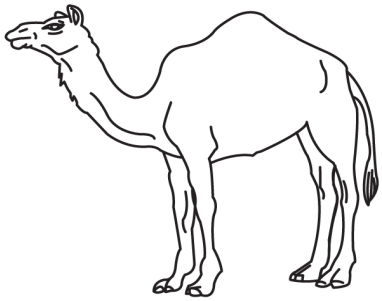
## NAMING



[ ]



[ ]



[ ]

___/3

## MEMORY

Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

| | FACE | VELVET | CHURCH | DAISY | RED |
|---|---|---|---|---|---|
| 1st trial | | | | | |
| 2nd trial | | | | | |

No points

## ATTENTION

Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2

___/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

___/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

___/3

## LANGUAGE

Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

___/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] _____ (N ≥ 11 words)

___/1

## ABSTRACTION

Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

___/2

## DELAYED RECALL

| | Has to recall words **WITH NO CUE** | FACE [ ] | VELVET [ ] | CHURCH [ ] | DAISY [ ] | RED [ ] | Points for UNCUED recall only |
|---|---|---|---|---|---|---|---|
| **Optional** | Category cue | | | | | | |
| | Multiple choice cue | | | | | | |

___/5

## ORIENTATION

[ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

___/6

 Version 7.1

# DIGIT SYMBOL CODING

**TOTAL SCORE (0 - 135) = _____**

# LOGICAL MEMORY - DELAYED RECALL

## Delayed Recall

☐ Story cue given

| Item | Detail | 1-Point Criteria | Score | |
|---|---|---|---|---|
| 1. | Ruth | *Ruth* or Ruthie | 0 | 1 |
| 2. | and Paul | *Paul* or Paulie | 0 | 1 |
| 3. | have been friends | *friends* (in any context) | 0 | 1 |
| 4. | for thirty | *thirty* (in any context) is required | 0 | 1 |
| 5. | years. | *year(s)* is required | 0 | 1 |
| 6. | They meet | *meet* (any indication of intentionally getting together) | 0 | 1 |
| 7. | every | *every* (in reference to Tuesday only) or *on Tuesdays* | 0 | 1 |
| 8. | Tuesday | *Tuesday(s)* (in any context) is required | 0 | 1 |
| 9. | at Alma's | *Alma's* (in any context) is required | 0 | 1 |
| 10. | Diner | *Diner* is required | 0 | 1 |
| 11. | for breakfast | *breakfast* (in any context) is required | 0 | 1 |
| 12. | and then they go for a walk | indication that they walk (e.g. stroll) | 0 | 1 |
| 13. | in Mason | *Mason* (in any context) is required | 0 | 1 |
| 14. | Park. | *Park* (in any context) is required | 0 | 1 |

Use the space below to write the examinee's verbatim responses if needed.

**Delayed Recall Total** (maximum = 14) ☐

## Questionnaire 3 (PHQ-9)

| **Over the last 2 weeks, how often have you been bothered by any of the following problems?** ***(use " ✓ " to indicate your answer)*** | | **Not at all** | **Several Days** | **More than half the days** | **Nearly Every Day** |
|---|---|---|---|---|---|
| 1. | Little interest or pleasure in doing things | ☐ | ☐ | ☐ | ☐ |
| 2. | Feeling down, depressed, or hopeless | ☐ | ☐ | ☐ | ☐ |
| 3. | Trouble falling or staying asleep, or sleeping too much | ☐ | ☐ | ☐ | ☐ |
| 4. | Feeling tired or having little energy | ☐ | ☐ | ☐ | ☐ |
| 5. | Poor appetite or overeating | ☐ | ☐ | ☐ | ☐ |
| 6. | Feeling bad about yourself -- or that you are a failure or have let yourself or your family down | ☐ | ☐ | ☐ | ☐ |
| 7. | Trouble concentrating on things, such as reading the newspaper or watching television | ☐ | ☐ | ☐ | ☐ |
| 8. | 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 | ☐ | ☐ | ☐ | ☐ |
| 9. | Thoughts that you would be better off dead, or of hurting yourself in some way | ☐ | ☐ | ☐ | ☐ |

| | | |
|---|---|---|
| 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** | _____ |

# SPRINT Standard BP Management Form
# 1M, 6M, 12M, 24M, 36M, 48M, 60M, and 72M Visits

| | | | |
|---|---|---|---|
| Participant Name: | _____ | Date of Visit: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| Participant ID: | ___ ___ ___ ___ ___ ___ ___ ___ | Form Completed by: | __ __ __ __ |
| Visit: ASK | Site: ___ ___ ___ | Date Entered: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| | | Data Entered by: | |

**Part A. Previous Blood Pressure ____/____ mm Hg at ____ M Visit on __ __/__ __/__ __**

**Part B. Current Blood Pressure (Cuff Size used at _____ was _____ )**

1. ☐ Check here if measurement was not performed using the study automated device.

Seated Measurements

| | Systolic | Diastolic | Heart Rate |
|---|---|---|---|
| 1st | _____ mmHg | _____ mmHg | _____ bpm |
| 2nd | _____ mmHg | _____ mmHg | _____ bpm |
| 3rd | _____ mmHg | _____ mmHg | _____ bpm |
| Average | _____ mmHg | _____ mmHg | _____ bpm |

2. ☐ Check here and SKIP to Part C if participant is unable to stand.

Standing Measurement (@ 1 minute)

| Systolic | Diastolic | Heart Rate |
|---|---|---|
| _____ mmHg | _____ mmHg | _____ bpm |

3. Did participant experience dizziness or light headed feelings when standing for this exam?

☐ No

☐ Yes

## Part C. Treatment Algorithm

4. Is the current seated SBP ≥ 160 mm Hg or ≥ 140 at last two visits, or is current seated DBP ≥ 100 mm Hg or ≥ 90 at last two visits?

- ☐ No
- ☐ Yes

If yes, the protocol requires intensification of therapy (medication added or dose increased).
Will therapy be intensified at this visit?

- ☐ No; Skip to question 6 below
- ☐ Yes; **STOP HERE and complete Medication Log**

5. Is the current seated SBP < 130 mm Hg or < 135 last two visits?

- ☐ No; **STOP HERE and complete Medication Log**
- ☐ Yes

If yes, the protocol recommends therapy be stepped down (medication removed or dose reduced).
Will therapy be stepped down at this visit?

- ☐ No; Continue with question 6 below
- ☐ Yes; **STOP HERE and complete Medication Log**

6. Specify reason(s) protocol mandated changes were not made.

- ☐ Addressed adherence problem
- ☐ Participant refusal
- ☐ In consultation with CCN, decision made not to alter therapy for this participant
- ☐ Other (specify: _____ )

**SPRINT Standard BP Management Form**
**2M, 3M, 9M, PRN and non-annual visits after the first year**

| | | | |
|---|---|---|---|
| Participant Name: | _____ | Date of Visit: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| Participant ID: | ___ ___ ___ ___ ___ ___ ___ ___ | Form Completed by: | __ __ __ __ |
| Visit: ASK | Site: ___ ___ ___ | Date Entered: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| | | Data Entered by: | __ __ __ __ |

**Part A. Previous Blood Pressure ____/____ mm Hg at ____ M Visit on __ __/__ __/__ __**

**Part B. Current Blood Pressure (Cuff Size used at _____ was _____ )**

1. ☐ Check here if measurement was not performed using the study automated device.

| | Seated Measurements | | |
|---|---|---|---|
| | Systolic | Diastolic | Heart Rate |
| 1st | _____ mmHg | _____ mmHg | _____ bpm |
| 2nd | _____ mmHg | _____ mmHg | _____ bpm |
| 3rd | _____ mmHg | _____ mmHg | _____ bpm |
| Average | _____ mmHg | _____ mmHg | _____ bpm |

**Part C. Treatment Algorithm**

2. Is the current seated SBP ≥ 160 mm Hg or ≥ 140 at last two visits, or is current seated DBP ≥ 100 mm Hg or ≥ 90 at last two visits?

☐ No
☐ Yes

If yes, the protocol requires intensification of therapy (medication added or dose increased).
Will therapy be intensified at this visit?

☐ No; Skip to question 4
☐ Yes; **STOP HERE and complete Medication Log**

3. Is the current seated SBP < 130 mm Hg or < 135 last two visits?

☐ No; **STOP HERE and complete Medication Log**
☐ Yes

If yes, the protocol recommends therapy be stepped down (medication removed or dose reduced).
Will therapy be stepped down at this visit?

☐ No; Continue with question 4
☐ Yes; **STOP HERE and complete Medication Log**

4. Specify reason(s) protocol mandated changes were not made.
   - ☐ Addressed adherence problem
   - ☐ Participant refusal
   - ☐ In consultation with CCN, decision made not to alter therapy for this participant
   - ☐ Other (specify: _____ )

# SPRINT Self-Administered Women's Health

| | | | |
|---|---|---|---|
| Participant ID: | ___ ___ ___ ___ ___ ___ ___ ___ | Date of Visit: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| Visit: ASK | Site: ___ ___ ___ | Form Completed by: | __ __ __ __ |
| | | Date Entered: | __ __ / __ __ / 20 __ __ (mm/dd/yyyy) |
| | | Data Entered by: | __ __ __ __ |

The questions below will help us understand how blood pressure treatment may affect sexual functioning. There are no right or wrong answers.

**Please complete the first 3 questions even if you have not been sexually active in the past 4 weeks.**

Also, although complete data is important to the study, if you feel uncomfortable answering any of these questions, you may skip them.

| **Over the past 4 weeks:** | | | | | |
|---|---|---|---|---|---|
| How **satisfied** have you been with your overall sexual life? | 1 ☐ Very dissatisfied | 2 ☐ Moderately dissatisfied | 3 ☐ About equally satisfied and dissatisfied | 4 ☐ Moderately satisfied | 5 ☐ Very satisfied |
| How **often** did you feel sexual desire or interest? | 1 ☐ Almost never or never | 2 ☐ A few times (less than half the time) | 3 ☐ Sometimes (about half the time) | 4 ☐ Most times (more than half the time) | 5 ☐ Almost always or always |
| How would you rate your **level** (degree) of sexual desire or interest? | 1 ☐ Very low or none at all | 2 ☐ Low | 3 ☐ Moderate | 4 ☐ High | 5 ☐ Very High |
| **Over the past 4 weeks:** | | | | | |
| Have you engaged in sexual activity of any kind with a partner and/or by yourself (masturbation)? | 0 ☐ No **(end of questionnaire)** | | | | |
| | 1 ☐ Yes **(continue to the next page)** | | | | |

| **Over the past 4 weeks:** | | | | | |
|---|---|---|---|---|---|
| How **often** did you feel sexually aroused ("turned on") during sexual activity or intercourse? | 1 ☐ Almost never or never | 2 ☐ A few times (less than half the time) | 3 ☐ Sometimes (about half the time) | 4 ☐ Most times (more than half the time) | 5 ☐ Almost always or always |
| How would you rate your **level** of sexual arousal ("turn on") during sexual activity or intercourse? | 1 ☐ Very low or none at all | 2 ☐ Low | 3 ☐ Moderate | 4 ☐ High | 5 ☐ Very High |
| How **confident** were you about becoming sexually aroused during sexual activity or intercourse? | 1 ☐ Very low or no confidence | 2 ☐ Low confidence | 3 ☐ Moderate confidence | 4 ☐ High confidence | 5 ☐ Very High confidence |
| How **often** have you been satisfied with your arousal (excitement) during sexual activity or intercourse? | 1 ☐ Almost never or never | 2 ☐ A few times (less than half the time) | 3 ☐ Sometimes (about half the time) | 4 ☐ Most times (more than half the time) | 5 ☐ Almost always or always |
| How **often** did you become lubricated ("wet") during sexual activity or intercourse? | 1 ☐ Almost never or never | 2 ☐ A few times (less than half the time) | 3 ☐ Sometimes (about half the time) | 4 ☐ Most times (more than half the time) | 5 ☐ Almost always or always |
| How **difficult** was it to become lubricated ("wet") during sexual activity or intercourse? | 5 ☐ Not difficult | 4 ☐ Slightly difficult | 3 ☐ Difficult | 2 ☐ Very difficult | 1 ☐ Extremely difficult or impossible |
| How often did you **maintain** your lubrication ("wetness") until completion of sexual activity or intercourse? | 1 ☐ Almost never or never | 2 ☐ A few times (less than half the time) | 3 ☐ Sometimes (about half the time) | 4 ☐ Most times (more than half the time) | 5 ☐ Almost always or always |
| How **difficult** was it to maintain your lubrication ("wetness") until completion of sexual activity or intercourse? | 5 ☐ Not difficult | 4 ☐ Slightly difficult | 3 ☐ Difficult | 2 ☐ Very difficult | 1 ☐ Extremely difficult or impossible |
| When you had sexual stimulation or intercourse, how **often** did you reach orgasm (climax)? | 1 ☐ Almost never or never | 2 ☐ A few times (less than half the time) | 3 ☐ Sometimes (about half the time) | 4 ☐ Most times (more than half the time) | 5 ☐ Almost always or always |
| When you had sexual stimulation or intercourse, how **difficult** was it for you to reach orgasm (climax)? | 5 ☐ Not difficult | 4 ☐ Slightly difficult | 3 ☐ Difficult | 2 ☐ Very difficult | 1 ☐ Extremely difficult or impossible |

| **Over the past 4 weeks:** | | | | | |
|---|---|---|---|---|---|
| How **satisfied** were you with your ability to reach orgasm (climax) during sexual activity or intercourse? | 1 ☐ Very dissatisfied | 2 ☐ Moderately dissatisfied | 3 ☐ About equally satisfied and dissatisfied | 4 ☐ Moderately Satisfied | 5 ☐ Very Satisfied |
| How **satisfied** have you been with your sexual relationship with your partner? | 1 ☐ Very dissatisfied | 2 ☐ Moderately dissatisfied | 3 ☐ About equally satisfied and dissatisfied | 4 ☐ Moderately Satisfied | 5 ☐ Very Satisfied |
| How **satisfied** have you been with the amount of emotional closeness during sexual activity between you and your partner? | 1 ☐ Very dissatisfied | 2 ☐ Moderately dissatisfied | 3 ☐ About equally satisfied and dissatisfied | 4 ☐ Moderately Satisfied | 5 ☐ Very Satisfied |
| How **often** did you experience discomfort or pain *during* vaginal penetration? | 5 ☐ Almost never or never | 4 ☐ A few times (less than half the time) | 3 ☐ Sometimes (about half the time) | 2 ☐ Most times (more than half the time) | 1 ☐ Almost always or always |
| How **often** did you experience discomfort or pain *following* vaginal penetration? | 5 ☐ Almost never or never | 4 ☐ A few times (less than half the time) | 3 ☐ Sometimes (about half the time) | 2 ☐ Most times (more than half the time) | 1 ☐ Almost always or always |
| How would you rate your **level** (degree) of discomfort or pain during or following vaginal penetration? | 5 ☐ Very low or none at all | 4 ☐ Low | 3 ☐ Moderate | 2 ☐ High | 1 ☐ Very High |