

Center Number: \_\_\_\_\_ Participant Number: \_\_\_\_\_ Participant's Initials: \_\_\_\_\_  
first middle last

## Clinic Weight

Weight date and time: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ : \_\_\_\_\_  
day month year 00:00 to 23:59

Staff initials: \_\_\_\_\_  
first middle last

OR Not done → Specify reason (use Codelist below): \_\_\_\_\_

Clinic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time):

Weight 1: \_\_\_\_\_ . \_\_\_\_\_ kg

Weight 2: \_\_\_\_\_ . \_\_\_\_\_ kg

Weight 3: \_\_\_\_\_ . \_\_\_\_\_ kg

Weight of gown: \_\_\_\_\_ . \_\_\_\_\_ kg

## Vital Signs

Assessment date and time: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ : \_\_\_\_\_  
day month year 00:00 to 23:59

If waist measurement not done → Specify reason (use codelist below): \_\_\_\_\_

**1 Natural waist measurement**  
 (if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third time):

Staff initials: \_\_\_\_\_  
first middle last

Natural waist measurement 1: \_\_\_\_\_ . \_\_\_\_\_ cm

Natural waist measurement 2: \_\_\_\_\_ . \_\_\_\_\_ cm

Natural waist measurement 3: \_\_\_\_\_ . \_\_\_\_\_ cm

**2 Umbilical point waist measurement** (if the first two measurements are more than 1.0 cm apart, measure umbilical point waist circumference a third time):

Umbilical point waist measurement 1: \_\_\_\_\_ . \_\_\_\_\_ cm

Umbilical point waist measurement 2: \_\_\_\_\_ . \_\_\_\_\_ cm

Umbilical point waist measurement 3: \_\_\_\_\_ . \_\_\_\_\_ cm

**3 Pulse:** \_\_\_\_\_ bpm OR Not done → Specify reason (use codelist below): \_\_\_\_\_

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first middle last

**4 Temperature:** \_\_\_\_\_ . \_\_\_\_\_ °C OR Not done → Specify reason (use codelist below): \_\_\_\_\_

Staff initials: \_\_\_\_\_  
first middle last

**5 Respirations:** \_\_\_\_\_ per minute OR Not done → Specify reason (use codelist below): \_\_\_\_\_

Staff initials: \_\_\_\_\_  
first middle last

**6 Blood pressure** (check only one): ☐<sub>1</sub> Left arm ☐<sub>2</sub> Right arm

Staff initials: \_\_\_\_\_  
first middle last

**6a Blood pressure 1:** \_\_\_\_\_ / \_\_\_\_\_ mm Hg **Time:** \_\_\_\_\_ : \_\_\_\_\_  
systolic diastolic 00:00 to 23:59 OR Not done →  
 Specify reason (use codelist below): \_\_\_\_\_

**6b Blood pressure 2:** \_\_\_\_\_ / \_\_\_\_\_ mm Hg **Time:** \_\_\_\_\_ : \_\_\_\_\_  
systolic diastolic 00:00 to 23:59

**6c Blood pressure 3:** \_\_\_\_\_ / \_\_\_\_\_ mm Hg **Time:** \_\_\_\_\_ : \_\_\_\_\_  
systolic diastolic 00:00 to 23:59

**Not Done Codelist:** 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required

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### 12-Lead ECG

| Date and Time   | Findings  | Staff Initials   |
|---|---|--|
| <div> <div> <div>____</div> <div>____</div> <div>____</div> </div> <div> <div>____</div> <div>____</div> <div>____</div> </div> <div> <div>____</div> <div>____</div> <div>____</div> </div> </div> <div> <div>day</div> <div>month</div> <div>year</div> </div> <div> <div>00:00 to 23:59</div> </div> | <b>Is ECG</b> (check only one):<br><input type="checkbox"/> <sub>1</sub> Normal<br><input type="checkbox"/> <sub>2</sub> Abnormal, not clinically significant (specify): _____<br><input type="checkbox"/> <sub>3</sub> Abnormal, clinically significant (specify): _____ | <div>____</div> <div>____</div> <div>____</div> <div>first middle last</div> |
| <b>OR Not done → Specify reason</b><br>(see codelist below): _____  |   |  |

### Safety Labs

Date and time of last meal: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ : \_\_\_\_  
day month year 00:00 to 23:59

Date and time of sample collection: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ : \_\_\_\_  
day month year 00:00 to 23:59

| Sample | Sample Complete?  | If Not Done, Reason<br>(Use codelist below) | Staff Initials   |
|--------|---|---|--|
| Blood  | <input type="checkbox"/> <sub>0</sub> No<br><input type="checkbox"/> <sub>1</sub> Yes | _____                                       | <div>____</div> <div>____</div> <div>____</div> <div>first middle last</div> |
| Urine  | <input type="checkbox"/> <sub>0</sub> No<br><input type="checkbox"/> <sub>1</sub> Yes | _____                                       | <div>____</div> <div>____</div> <div>____</div> <div>first middle last</div> |

### Contraception

If Not Done → Specify reason (use codelist below): \_\_\_\_\_

Contraception method (females only):

- ☐ None **OR Check all that apply:**  
☐ Oral contraceptive → Specify: \_\_\_\_\_  
**Record on Concomitant Medications page**  
☐ Other → Specify (e.g., barrier, IUD): \_\_\_\_\_

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Date completed: \_\_\_\_/\_\_\_\_/\_\_\_\_ OR Not done → Specify reason (use codelist below): \_\_\_\_  
day month year

### BDI-II

**Instructions:** This questionnaire consists of 21 groups of statements. Please read each group of statements carefully and then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including today. Check the box beside the statement you have picked. Be sure that you check only one statement for each group, including item 16 and item 18.

- 1 Sadness:**
  - ☐<sub>0</sub> I do not feel sad
  - ☐<sub>1</sub> I feel sad much of the time
  - ☐<sub>2</sub> I am sad all of the time
  - ☐<sub>3</sub> I am so sad or unhappy that I can't stand it
- 2 Pessimism:**
  - ☐<sub>0</sub> I am not discouraged about my future
  - ☐<sub>1</sub> I feel more discouraged about my future than I used to be
  - ☐<sub>2</sub> I do not expect things to work out for me
  - ☐<sub>3</sub> I feel my future is hopeless and will only get worse
- 3 Past failure:**
  - ☐<sub>0</sub> I do not feel like a failure
  - ☐<sub>1</sub> I have failed more than I should have
  - ☐<sub>2</sub> As I look back, I see a lot of failures
  - ☐<sub>3</sub> I feel I am a total failure as a person
- 4 Loss of pleasure:**
  - ☐<sub>0</sub> I get as much pleasure as I ever did from the things I enjoy
  - ☐<sub>1</sub> I don't enjoy things as much as I used to
  - ☐<sub>2</sub> I get very little pleasure from the things I used to enjoy
  - ☐<sub>3</sub> I can't get any pleasure from the things I used to enjoy
- 5 Guilty feelings:**
  - ☐<sub>0</sub> I don't feel particularly guilty
  - ☐<sub>1</sub> I feel guilty over many things I have done or should have done
  - ☐<sub>2</sub> I feel quite guilty most of the time
  - ☐<sub>3</sub> I feel guilty all of the time
- 6 Punishment feelings:**
  - ☐<sub>0</sub> I don't feel I am being punished
  - ☐<sub>1</sub> I feel I may be punished
  - ☐<sub>2</sub> I expect to be punished
  - ☐<sub>3</sub> I feel I am being punished
- 7 Self-dislike:**
  - ☐<sub>0</sub> I feel the same about myself as ever
  - ☐<sub>1</sub> I have lost confidence in myself
  - ☐<sub>2</sub> I am disappointed in myself
  - ☐<sub>3</sub> I dislike myself

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### BDI-II (continued)

#### 8 Self-criticalness:

- ☐<sub>0</sub> I don't criticize or blame myself more than usual
- ☐<sub>1</sub> I am more critical of myself than I used to be
- ☐<sub>2</sub> I criticize myself for all of my faults
- ☐<sub>3</sub> I blame myself for everything bad that happens

#### 9 Suicidal thoughts or wishes:

- ☐<sub>0</sub> I don't have any thoughts of killing myself
- ☐<sub>1</sub> I have thoughts of killing myself but I would not carry them out
- ☐<sub>2</sub> I would like to kill myself
- ☐<sub>3</sub> I would kill myself if I had the chance

#### 10 Crying:

- ☐<sub>0</sub> I don't cry any more than I used to
- ☐<sub>1</sub> I cry more than I used to
- ☐<sub>2</sub> I cry over every little thing
- ☐<sub>3</sub> I feel like crying, but I can't

#### 11 Agitation:

- ☐<sub>0</sub> I am no more wound up or restless than usual
- ☐<sub>1</sub> I feel more restless or wound up than usual
- ☐<sub>2</sub> I am so restless or agitated that it's hard to stay still
- ☐<sub>3</sub> I am so restless or agitated that I have to keep moving or doing something

#### 12 Loss of interest:

- ☐<sub>0</sub> I have not lost interest in other people or activities
- ☐<sub>1</sub> I am less interested in other people or things than before
- ☐<sub>2</sub> I have lost most of my interest in other people or things
- ☐<sub>3</sub> It's hard to get interested in anything

#### 13 Indecisiveness:

- ☐<sub>0</sub> I make decisions about as well as ever
- ☐<sub>1</sub> I find it more difficult to make decisions than usual
- ☐<sub>2</sub> I have much greater difficulty in making decisions than I used to
- ☐<sub>3</sub> I have trouble making my decisions

#### 14 Worthlessness:

- ☐<sub>0</sub> I do not feel I am worthless
- ☐<sub>1</sub> I don't consider myself as worthwhile and useful as I used to
- ☐<sub>2</sub> I feel more worthless as compared to other people
- ☐<sub>3</sub> I feel utterly worthless

#### 15 Loss of energy:

- ☐<sub>0</sub> I have as much energy as ever
- ☐<sub>1</sub> I have less energy than I used to have
- ☐<sub>2</sub> I don't have enough energy to do very much
- ☐<sub>3</sub> I don't have enough energy to do anything

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first middle last

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Participant Number: \_\_\_\_

Participant's Initials:                       
first middle last

### BDI-II (continued)

**16 Changes in sleeping pattern:** ☐<sub>0</sub> I have not experienced any change in my sleeping pattern

☐<sub>1</sub> I sleep somewhat more than usual

☐<sub>2</sub> I sleep somewhat less than usual

☐<sub>3</sub> I sleep a lot more than usual

☐<sub>4</sub> I sleep a lot less than usual

☐<sub>5</sub> I sleep most of the day

☐<sub>6</sub> I wake up 1-2 hours early and can't get back to sleep

**17 Irritability:**

☐<sub>0</sub> I am no more irritable than usual

☐<sub>1</sub> I am more irritable than usual

☐<sub>2</sub> I am much more irritable than usual

☐<sub>3</sub> I am irritable all of the time

**18 Changes in appetite:**

☐<sub>0</sub> I have not experienced any change in my appetite

☐<sub>1</sub> My appetite is somewhat less than usual

☐<sub>2</sub> My appetite is somewhat greater than usual

☐<sub>3</sub> My appetite is much less than before

☐<sub>4</sub> My appetite is much greater than usual

☐<sub>5</sub> I have no appetite at all

☐<sub>6</sub> I crave food all of the time

**19 Concentration difficulty:**

☐<sub>0</sub> I can concentrate as well as ever

☐<sub>1</sub> I can't concentrate as well as usual

☐<sub>2</sub> It's hard to keep my mind on anything for very long

☐<sub>3</sub> I find I can't concentrate on anything

**20 Tiredness or fatigue:**

☐<sub>0</sub> I am no more tired or fatigued than usual

☐<sub>1</sub> I get more tired or fatigued more easily than usual

☐<sub>2</sub> I am too tired or fatigued to do a lot of the things I used to do

☐<sub>3</sub> I am too tired or fatigued to do most of the things I used to do

**21 Loss of interest in sex:**

☐<sub>0</sub> I have not noticed any recent change in my interest in sex

☐<sub>1</sub> I am less interested in sex than I used to be

☐<sub>2</sub> I am much less interested in sex now

☐<sub>3</sub> I have lost interest in sex completely

Participant's Initials:                       
first middle last