

Month 9 Submission

PAGEID = 156

| | Center Number: Participant Number: | Participant's Initials: First middle last |
|-----|--|---|
| C | linic Weight | |
| w | eight date and time:/ _{month} /::: _: | Staff initials: |
| | R Not done → Specify reason (use Codelist below): | DATEHDR (TYPE 4) |
| Cli | nic weight (if the first two measurements are more than 0.1 kg apart, measure weight a third time) |) : |
| W | eight 1: SAME AS PAGE 4 | |
| W | eight 2: kg | WEIGHT (TYPE 4) |
| W | eight 3: kg | |
| W | eight of gown: kg | |
| V | ital Signs | |
| As | sessment date and time:/ | |
| | If waist measurement not done → Specify reason (use codelist below): | VITALS (TYPE 3) |
| ו' | Natural waist measurement (if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a third til | Staff initials: first middle last |
| | Natural waist measurement 1: cm SAME AS F | PAGE 29 |
| | 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, measurement point waist circumference a third time): | sure |
| | 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): | Staff initials: first middle lost |
| 4 | Temperature: °C OR Not done → Specify reason (use codelist below): | Staff initials: |
| 5 | Respirations: per minute OR Not done → Specify reason (use codelist below): | Staff initials: |
| 6 | Blood pressure (check only one): □₁ Left arm □₂ Right arm | Staff initials: |
| | 6a Blood pressure 1:/ mm Hg Time:: OR Not do Specify | ne → reason (use codelist below): |
| | 6b Blood pressure 2:/ mm Hg Time::: | |
| | 6c Blood pressure 3:/ mm Hg Time:: | |
| No | ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 | Instrument failure 5 Not required |



Month 9 Submission

PAGEID = **157**

| Center | Number: Participant N | tolliber: ra | rticipant's Initials: first middle last | | | |
|--|--|--|--|--|--|--|
| 12-Lead ECG | | | | | | |
| Date and Time | | Findings ECG (TYF | PE 4) Staff Initials | | | |
| DATEHDR (TYPE 4) | | SAME AS PAGE: | first middle last | | | |
| Safety Labs | | | | | | |
| Date and time of last meal: Date and time of sample collection: | | | | | | |
| Sample | Sample Complete? | If Not Done, Reason (Use codelist below) | Staff Initials | | | |
| Blood | □ ₀ No □ ₁ Yes | | first middle last | | | |
| Urine | □₀ No □₁ Yes | | first middle last | | | |
| Contraception | | | | | | |
| If Not Done → Specify reason (use codelist below): | | | | | | |
| Contraception method (females only): | Contraception method (females only): □ None OR Check all that apply: □ Oral contraceptive → SpecifyOUTCME2 (TYPE 4) | | | | | |
| SAME AS PAGE 95 | ☐ Other → Sp | Record on Concor pecify (e.g., barrier, IUD): | mitant Medications page | | | |
| Not Done Codelist: 1 Participant refused 2 Clinic | ian unable to obtain 3 Insuff | icient time 4 Instrument fail | ure 5 Not required | | | |



PAGEID = **161**

| | Center Number: Participant | Number: Participant's Initials: first middle last |
|------|--|---|
| Cli | inic Weight | |
| Wei | eight date and time:/ _{month} /: | Staff initials: |
| | Not done → Specify reason (use Codelist below): | DATEHDR (TYPE 4) |
| Clin | nic weight (if the first two measurements are more than 0.1 kg apart, measure we | ight a third time): |
| Wei | sight 1: kg SAME AS | PAGE 4 |
| Wei | eight 2: kg | WEIGHT (TYPE 4) |
| Wei | sight 3: kg | |
| Wei | sight of gown: kg | |
| _ | ital Signs | |
| Ass | sessment date and time:/ _{month} / :::: | |
| | If waist measurement not done → Specify reason (use codelist below): | _ VITALS (TYPE 3) |
| | Natural waist measurement (if the first two measurements are more than 1.0 cm apart, measure natural waist circum | Staff initials: first middle lost |
| | Natural waist measurement 1: cm | SAME AS PAGE 29 |
| | Natural waist measurement 2: cm | |
| | Natural waist measurement 3: cm | |
| | 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) | : Staff initials: iniddle lost |
| 4 | Temperature:°C OR Not done → Specify reason (use coo | delist below): Staff initials: initials: |
| 5 | Respirations: per minute OR Not done → Specify reason (use cod | c. ff. w. l |
| 6 | Blood pressure (check only one): Left arm Right arm | Staff initials: |
| | 6a Blood pressure 1:/ mm Hg | OR Not done → |
| | | |
| | 6b Blood pressure 2:/ mm Hg Time:: | _ |
| | 6¢ Blood pressure 3:/ mm Hg Time::: | _ |
| Not | t Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insuf | ficient time 4 Instrument failure 5 Not required |



PAGEID = 162

| Center | Number: Participant | Number: Par | rticipant's Initials: | | | |
|---|---------------------------|---|-----------------------|--|--|--|
| 12-Lead ECG | | | | | | |
| Date and Time | | Findings ECG (TYP | E 4) Staff Initials | | | |
| DATEHDR (TYPE 4) ——————————————————————————————————— | | SAME AS PAGE (silly significant (specify): | first middle last | | | |
| Safety Labs | | | | | | |
| Date and time of last meal: | | | | | | |
| Sample | Sample Complete? | If Not Done, Reason (Use codelist below) | Staff Initials | | | |
| Blood | □₀ No □₁ Yes | SA | ME AS PAGE 30 | | | |
| Urine | □₀ No □₁ Yes | | first middle fost | | | |
| Pregnancy Test | | | | | | |
| Complete only for females. | | PREGTEST (| TYPE 4) | | | |
| Does participant have reproductive potential? □0 No □1 Yes → If Yes: Date urine pregnancy test p Results: □1 Negative □2 Positive | SAME AS PAC | | | | | |
| Net Dana Cadalists 1 Participant refused 2 Clinic | ian unahla ta ahtain 2 Ii | ficient time A Instrument feet | S Not required | | | |



PAGEID = **163**

| | | Center Number: | r: Partiapont Number: Partiapont's Initials: first middle last | | | | | |
|----|---|---------------------|--|--|--|--|--|--|
| D | oubly Labeled V | V ater (DLW) | | | | | | |
| 1 | | osing:/// | DIWLIDD (TVDE 4) | | | | | |
| 2 | DLW dose mixture ID an | nd bottle number: | CA | | | | | |
| 3 | Exact weight of DLW mix | xture:(| grams | | | | | |
| 4 | Urine samples: | AME AS PAGE 114 | DLWCHT (TYPE 4)PS | | | | | |
| | Collection | Sample | Date and Time Collected | | | | | |
| | Pre dosing (PD) | PDa | / | | | | | |
| | | PDb | / | | | | | |
| | Day 0 (Visit 1) | D0a | / | | | | | |
| | | DOP | / | | | | | |
| | Day 7 (Visit 2) | D7a | / | | | | | |
| | | D7b | | | | | | |
| | Day 14 (Visit 4) | D14a | | | | | | |
| | | D14b | / | | | | | |
| 5 | Affix CRF page label(s) corresponding to this urine sample set: Affix | | | | | | | |
| No | Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required | | | | | | | |



PAGEID = 164

| Center Number: Participant Num | | mber: Participant's Initials: | | | | |
|---|-----------------------|-------------------------------|-------------------|----------------------------------|--|--|
| Physical Examination | | | | | | |
| Date of examination:/ | _/ | _ | | Staff initials: | | |
| OR Not done → Specify reason (use co | | | DACE 22 | DATEHDR (TYPE 4) | | |
| | | Assessments | | | | |
| Body System | Normal | nal Abnormal Not Done | | If Abnormal or Not Done: Explain | | |
| General appearance: | | □₀→ | □ ₉₇ → | | | |
| 2 Head, Ears, Eyes, Nose, Throat: | \square_1 | □₀→ | □ ₉₇ → | PEXAM (TYPE 4)PS | | |
| 3 Neck: | | □₀→ | □ ₉₇ → | SAME AS PAGE 32 | | |
| 4 Heart: | | □₀→ | □ ₉₇ → | Grinie Alo I Aloe de | | |
| 5 Lungs: | \Box_1 | □₀→ | □ ₉₇ → | | | |
| 6 Abdomen: | □₁ | □₀→ | □ ₉₇ → | | | |
| 7 Lymph nodes: | \Box_1 | □₀→ | □ ₉₇ → | | | |
| 8 Extremities/Skin: | | □₀→ | □ ₉₇ → | | | |
| 9 Neurological: | | □₀→ | □ ₉₇ → | | | |
| 10 Musculoskeletal: | | □₀→ | ₉₇ → | | | |
| | Normal | Abnormal | Not Done* | | | |
| 11 Genitourinary: | | □₀→ | □ ₉₇ → | | | |
| 12 Breast: | \Box_1 | □₀→ | □ ₉₇ → | | | |
| Physician's Signature | | | | | | |
| Investigator: | Investigator: Date:// | | | | | |
| t Not done at this evention at an OB Polarice | | | | | | |

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



PAGEID = 165

| | Center Number: | Participant Number: | Participant's Initials: | | | | |
|--|--|---------------------|------------------------------------|--|--|--|--|
| DXA Scan | | | | | | | |
| Has the participant taken a calcium sup □ ₀ No □ ₁ Yes → If Yes: Proceed with | , | | XASCAN (TYPE 4) orm the QA Center. | | | | |
| Were any studies involving barium or re | | • | scheduled DXA exam? | | | | |
| □ _o No □ ₁ Yes | SAME AS F | PAGE 35 | | | | | |
| DXA Scan OR OR ON ON | | | | | | | |
| Date of scan:/ | _ | Date of rescan:/ | | | | | |
| Area Scanned Check all that apply | If Not Done, Reason (Use codelist below) | | a Scanned all that apply | | | | |
| ☐ Whole body | | ☐ Whole | body | | | | |
| Forearm | | ☐ Forearm | 1 | | | | |
| Spine | | Spine | | | | | |
| Hip | | Hip | | | | | |



| PAGEID = 1/2 | | Center Number: | Participant N | Number: | Participant's In | nitials: |
|--------------------|-----------------------|---|-----------------|--------------------------------|--------------------------------|------------------------|
| Date completed: | / | OR Not don | e → Specify re | ason (use codelist be | :low): | |
| Profile of Mo | | SAME A | S PAGE 36 | | DATEHDR (| TYPE 4) |
| | | feel right now by ch | necking one box | x for each of the w | ords listed below. | |
| | ·ling | Not At All | A Little | Moderately | POMS (T Quite A Bit | YPE 4)PS Extremely |
| 1 Friendly | - | SAME AS PA | | | | |
| 2 Tense | | | | <u></u> | 3 | <u> </u> |
| | | | <u>U</u> 1 | | 3 | |
| 3 Angry | | | <u> </u> | | 3 | 4 |
| 4 Worn out | | | | | 3 | 4 |
| 5 Unhappy | | | | | 3 | 4 |
| 6 Clear-headed | | | | | З | 4 |
| 7 Lively | | \square_{o} | | | 3 | 4 |
| 8 Confused | | \square_{o} | | | | 4 |
| 9 Sorry for thin | gs done | | | | 3 | 4 |
| 10 Shaky | | \square_{o} | \square_1 | \square_{2} | | \square_4 |
| 11 Listless | | | | | | 4 |
| 12 Peeved | | \square_{o} | \square_1 | | | 4 |
| 13 Considerate | | | | | 3 | 4 |
| 14 Sad | | \square_{o} | \square_1 | \square_{2} | | \square_4 |
| 15 Active | | | | | | 4 |
| 16 On edge | | \square_{o} | \square_1 | \square_{2} | \square_3 | \square_4 |
| 17 Grouchy | | | | | \square_3 | \square_4 |
| 18 Blue | | \square_{o} | | | \square_3 | \square_4 |
| 19 Energetic | | | | | \square_3 | 4 |
| 20 Panicky | | | | \square_2 | \square_3 | |
| | | cNair Ph.D., and JW P. Heuchert, Victoria Park Ave., Toronto, ON A | | license to Multi-Health System | ns Inc. All rights reserved. I | n the U.S.A., P.O. Box |
| Not Done Codelist: | 1 Participant refused | 2 Clinician unable to | obtain 3 Insuff | icient time 4 Instru | ment failure 5 No | ot required |

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Participant's Initials: first middle last

Durham NC 27705

Send to DCRI I



PAGEID = 173

| | Center Number: | Participant Number: | | Participant's I | nitials: |
|---------------------------|-------------------|---------------------|---------------|-----------------|---------------|
| Profile of Mood States (d | ontinued) | | | | |
| Feeling | Not At All | A Little | Moderately | Quite A Bit | Extremely |
| 21 Hopeless | | | | MS (TYPE 4) | PS |
| 22 Relaxed | □, SAME | AS PAGE 43 | | \square_3 | |
| 23 Unworthy | | □, | | \square_3 | \square_4 |
| 24 Spiteful | \square_{o} | \square_1 | \square_2 | \square_3 | \square_4 |
| 25 Sympathetic | | □, | | \square_3 | \square_{4} |
| 26 Uneasy | \square_{o} | \square_1 | \square_2 | Пз | |
| 27 Restless | | | | \square_3 | |
| 28 Unable to concentrate | \square_{o} | \square_1 | | \square_3 | |
| 29 Fatigued | □₀ | | | \square_3 | |
| 30 Helpful | \square_{o} | \Box_1 | \square_{2} | Пз | |
| 31 Annoyed | \square_{\circ} | | | \square_3 | |
| 32 Discouraged | \square_{o} | | | \square_3 | |
| 33 Resentful | \square_{o} | | | \square_3 | _4 |
| 34 Nervous | \square_{o} | | | \square_3 | |
| 35 Lonely | | | | \square_3 | |
| 36 Miserable | □₀ | | | 3 | |
| 37 Muddled | □₀ | | | 3 | |
| 38 Cheerful | \square_{\circ} | | | \square_3 | |
| 39 Bitter | □₀ | | | □ ₃ | |
| 40 Exhausted | | | | | |
| 41 Anxious | | | | □ ₃ | |
| 42 Ready to fight | \square_{o} | \square_1 | | \square_3 | |
| 43 Good-natured | \square_{o} | □ ₁ | | 3 | 4 |

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Participant's Initials:



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| PAGEID = 174 | Center Number: _ | Participant Number: | | Participant's Initials: First middle last | | |
|---------------------------|------------------|---------------------|-----------------|---|-----------|--|
| Profile of Mood States | continued) | | | | | |
| Feeling | Not At All | A Little | Moderately | Quite A Bit | Extremely | |
| 44 Gloomy | \Box_{\circ} | | \bigsqcup_{2} | | PS □₄ | |
| 45 Desperate | SAME | E AS PAGE 44 | | 3 | 4 | |
| 46 Sluggish | \square_{o} | | | \square_3 | | |
| 47 Rebellious | | | | 3 | 4 | |
| 48 Helpless | | | | □₃ | | |
| 49 Weary | | | | | | |
| 50 Bewildered | | | | | | |
| 51 Alert | | | | | | |
| 52 Deceived | | | | Пз | | |
| 53 Furious | | | | | | |
| 54 Efficient | | | | Пз | | |
| 55 Trusting | | | | | | |
| 56 Full of pep | | | | Пз | | |
| 57 Bad-tempered | | | | | 4 | |
| 58 Worthless | | | | | | |
| 59 Forgetful | | | | 3 | | |
| 60 Carefree | | | | \square_3 | | |
| 61 Terrified | □₀ | | | \square_3 | 4 | |
| 62 Guilty | \square_{o} | | | □3 | □4 | |
| 63 Vigorous | | | \square_2 | \square_3 | 4 | |
| 64 Uncertain about things | | | | \square_3 | | |
| 65 Bushed | | | | □₃ | | |

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Participant's Initials:

first middle last



| Р | AGEID = 1/5 Center Number: Participant Num | ber: | | Participant ^e | 's Initials: | irst middle last | | |
|----|--|--------------------|-----------------|--------------------------|-----------------|------------------|--|--|
| Da | te completed: $\underline{\hspace{1cm}}_{day}/\underline{\hspace{1cm}}_{month}/\underline{\hspace{1cm}}_{year}$ OR Not done \rightarrow Specify reaso | n (use code | list below). | TEHD | R (TY | 'PE 4 | | |
| P | erceived Stress Scale (PSS) | | | | | 3 | | |
| In | Instructions: The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate how often you felt or thought a certain way. Please check only one answer for each question. | | | | | | | |
| | SAME AS PAGE 45 | Never | Almost Never | Some- times | Fairly Often | Very Often | | |
| 1 | In the last month, how often have you felt that you were unable to control the important things in your life? | | | | \square_3 | | | |
| 2 | In the last month, how often have you felt confident about your ability to handle your personal problems? | \square_{o} | \square_1 | \square_{2} | \square_3 | \square_4 | | |
| 3 | In the last month, how often have you felt that things were going your way? | | | | □₃ | | | |
| 4 | In the last month, how often have you felt difficulties were piling up so high that you could not overcome them? | | | | \square_3 | | | |
| No | ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficien | nt time 4 | Instrument I | failure 5 | Not requi | red | | |



| P. | AGEID = 176 | Center Number: | Participant | Number: | Partic | cipant's Initials | first middle last |
|-----|--|--|-------------------------|---------------------------------|-----------------------------|----------------------------|------------------------------|
| Dat | te completed:/ _{month} / | OR Not done SAME AS | → Specify re PAGE 36 | ason (use codel | ist below): DATEH | ĪDR (TY | PE 4) |
| Pi | ttsburgh Sleep Quality I | ndex (PSQI) | | | | | |
| lns | structions: The following questions re the most accurate reply fo | | | | | | |
| Dυ | ring the past month | SAME A | AS PAGE | 46 | PSQI1 | I(TYPE | 4) |
| 1 | When have you usually gone | to bed? :: : : : : : : : : : : : : : : : : : | _ | | | | |
| 2 | How long (in minutes) has it to | aken you to fall asl | eep each | night? | minutes | 5 | |
| 3 | When have you usually gotte | n up in the morning |]?: | 23:59 | | | |
| 4 | How many hours of actual sleep (This may be different than the number of hours | , , , | | | | | |
| 5 | During the past month, how a sleeping because you (check | • | | Not during the past month | Less than once a week | Once or twice a week | 3 or more times a week |
| | a Cannot get to sleep within | 30 minutes | | \square_{o} | \square_1 | | \square_3 |
| | b Wake up in the middle of t | he night or early m | orning | | | | З |
| | • Have to get up to use the b | oathroom | | | | | \square_3 |
| | d Cannot breathe comfortab | ly | | | | | 3 |
| | e Cough or snore loudly | | | | | | \square_3 |
| | f Feel too cold | | | | | | \square_3 |
| | g Feel too hot | | | \square_{0} | | | 3 |
| | h Have bad dreams | | | | | | \square_3 |
| | i Have pain | | | | | | \square_3 |
| | j Other reason(s), please de you have had trouble sleep reason(s): | • | | \Box_{0} | \square_1 | | \square_3 |
| 6 | During the past month, how a medicine (prescribed or "over the cou | and the second second | | | | | \square_3 |
| | 89,with permission from Elsevier Science. of Done Codelist: 1 Participant refused | 2 Clinician unable to obt | gin 3 Insuf | ficient time 4 I | nstrument failure | 5 Not re | quired 1 |
| .40 | | ASE2 ANNOTATIO | | | | cipant's Initials | |

Durham NC 27705



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| | | Center Number: | Participant I | Number: | Parti | cipant's Initials: | first middle last |
|----|---|-----------------------|---------------|----------------------|----------------------------------|-------------------------------|---------------------------------|
| Pi | ttsburgh Sleep Quality I | ndex (PSQI) (continue | ed) | | | | |
| | SAME AS PAGE 47 | PSQI2(TY | PE 3) | Never | Once or twice | Once or twice each week | 3 or more times each week |
| 7 | During the past month, how oft staying awake while driving, es social activity? | • | | \square_{o} | | | |
| | | | | No problem at all | Only a very slight problem | Somewhat of a problem | A very big problem |
| 8 | During the past month, how no been for you to keep up enthu | • | | \square_{0} | | | \square_3 |
| | | | | Very good | Fairly good | Fairly bad | Very bad |
| 9 | During the past month, how waquality overall? | vould you rate your | sleep | | | | З |

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| FAOLID = 170 | Center Number: | Participant Number: | Participant's Initials: | first middle last |
|--------------|----------------|---------------------|-------------------------|-------------------|
| | | | | |

Date completed: — oR Not done → Specify reason (use codelist below): —DATEHDR (TYPE 4) SAME AS PAGE 36

Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version

Instruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about sexual fantasies or daydreams, while another inquires about the kinds of sexual experiences that you have. You are also asked about the nature of your sexual arousal and the quality of your orgasm. There are also a few other questions about different areas of your sexual relationship.

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "O = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied."

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best describes your personal experience. DISFEM1 (TYPE 4)PS

If you have any questions, please ask the person who gave you the inventory for help.

SAME AS PAGE 48

Section 1—Sexual Cognition/Fantasy Not at Less 1 or 2 1 per 2 or 3 4 to 6 1 per 2 or 3 4 or During the past 30 days or since the last time all than 1 per per week per day per more you filled out this inventory, how often have month week week day per per you had thoughts, dreams, or fantasies about: month day 1.1 A sexually attractive person 1.2 Erotic parts of a man's body (e.g., face, shoulders, legs) 1.3 Erotic or romantic situations 1.4 Caressing, touching, undressing, or foreplay 1.5 Sexual intercourse, oral sex, touching to orgasm Copyright © 1987 by Leonard R. Derogatis, PhD.

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2 Clinician unable to obtain

Participant's Initials: first middle last

5 Not required

Durham NC 27705

4 Instrument failure

3 Insufficient time

Not Done Codelist: 1 Participant refused



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| Center N | lumber: | Po | articipant N | lumber: _ | | Par | ticipant's | Initials: _ | rst middle last |
|---|---------------|--------------------------------|------------------------|---------------|-----------------------|-----------------------|--------------|----------------------|----------------------------|
| Derogatis Interview for Sexual | Functi | on (DIS | F-SR) (F) | Female \ | /ersion (| continued |) | | |
| Section 2—Sexual Arousal SAME AS | PAGE 4 | 19 | | | DIS | SFEM1 | (TYF | PE 4)F | PS . |
| During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences? | Not at all | Less than 1 per month | 1 or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | 1 per day | 2 or 3 per day | 4 or more per day |
| 2.1 Feel sexually aroused while alone | □。 | | | | 4 | | □, | | □8 |
| 2.2 Actively seek sexual satisfaction | □。 | | | | | | □。 | | □8 |
| 2.3 Feel sexually aroused with a partner | | □, | | | | | □, | | □. |
| | Never | Rarely | Sometimes | Usually | Always | DISFE | M2 (| ГҮРЕ | 4)PS |
| 2.4 Have normal lubrication with masturbation | □。 | | | | □4 | | | | |
| 2.5 Have normal lubrication throughout sexual relations | □。 | | | | | | | | |

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| Center Nu | mber: | Po | articipant N | lumber: _ | | Po | ırticipant's | Initials: | rst middle last |
|---|---------------|--------------------------------|------------------------|---------------|-----------------------|-----------------------|----------------|----------------------|----------------------------|
| Derogatis Interview for Sexual I | Functi | on (DIS | F-SR) (F) | Female \ | ersion (| ontinue | d) | | |
| Section 3—Sexual Behavior/Experiences | SAM | E AS P | AGE 50 |) | DIS | SFEM [.] | 1 (TYF | PE 4)F | PS |
| During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities? | Not at all | Less than 1 per month | l or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | l per day | 2 or 3 per day | 4 or more per day |
| 3.1 Reading or viewing romantic or erotic books or stories | □. | | | □₃ | | ₅ | □ ₆ | □ ₇ | □8 |
| 3.2 Masturbation | | | | □₃ | □₄ | \square_5 | □6 | □7 | □8 |
| 3.3 Casual kissing and petting | | | | □₃ | □₄ | □ ₅ | □ ₆ | □ ₇ | □8 |
| 3.4 Sexual foreplay | □, | | | □₃ | □₄ | \square_5 | □6 | □, | □8 |
| 3.5 Sexual intercourse, oral sex, etc. | | | | | □4 | □ ₅ | □ ₆ | □ ₇ | □8 |
| Section 4—Orgasm | | | | | DIS | FEM: | 3 (TYF | PE 4)F | PS |
| During the past 30 days or since the last time you filled out this inventory, how satisfied have you been with the following? | Not at all | Slightly | Moderately | Highly | Extremely | | | | |
| 4.1 Your ability to have an orgasm | | | | | | | | | |
| 4.2 The intensity of your orgasm | □. | | | □₃ | □₄ | | | | |
| 4.3 The ability to have multiple orgasms (if typical for you) | | | | | _4 | | | | |
| 4.4 Feelings of closeness and togetherness with your partner | □, | | | 3 | | | | | |
| 4.5 Your sense of control (timing) of your orgasm | | | | | | | | | |
| 4.6 Feeling a sense of relaxation and well-being after orgasm | □. | | | □₃ | □4 | | | | |

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| | Center Number: | | Participant | Number: | | P | 'articipant' | s Initials: | irst middle last |
|---|--------------------------|--------------------------------|------------------------|------------------------|---------------------------|-----------------------|--------------|----------------------|----------------------------|
| Derogatis Interview for Sex | xual Func | tion (| DISF-SR) (| F) Female | Version | (continue | ed) | | |
| Section 5—Drive and Relationship | SAME | AS PA | GE 51 | С | ISFE | M1 (T | YPE 4 |)PS | |
| | Not at all | Less than 1 per month | 1 or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | 1 per day | 2 or 3 per day | 4 or more per day |
| 5.1 With the partner of your choice what would be your ideal frequency of sexual intercourse | | | | \square_3 | 4 | 5 | □6 | | 8 |
| | Not at all | Slightly | Moderately | Highly | Extren <mark>ie</mark> ly | SFEM | 13 (TY | PE 4)F | PS |
| 5.2 During this period, how interested have you been in se | x? | | | □₃ | 4 | | | | |
| 5.3 During this period, how satisfie have you been with your personal relationship with you sexual partner? | | | | | □₄ DI | SFEM | 14 (TY | PE 4)F | PS . |
| | Could not be worse | Very poor | Poor | Somewhat inadequate | Adequate | Above average | Good | Very good | Could not be better |
| 5.4 In general, what would repres the best description of the qua of your sexual functioning? | | | | □₃ | 4 | | | | |

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DATEHDR (TYPE 4)

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| Data completed: / / | OP Not done - Specify reason //see codelist below! | | |

Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version

Instruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about sexual fantasies or daydreams, while another inquires about the kinds of sexual experiences that you have. You are also asked about the nature of your sexual arousal and the quality of your orgasm. There are also a few other questions about different areas of your sexual relationship.

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "O = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied."

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best describes your personal experience.

If you have any questions, please ask the person who gave you the inventory for help.

DISMALE1 (TYPE 4)PS

| Section 1—Sexual Cognition/Fantasy | SAME A | AS PAG | SE 52 | | | | | | |
|--|---------------|--------------------------------|------------------------|---------------|-----------------------|-----------------------|--------------|----------------------|----------------------------|
| During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about: | Not at all | Less than 1 per month | 1 or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | 1 per day | 2 or 3 per day | 4 or more per day |
| 1.1 A sexually attractive person | □₀ | | | | □4 | | □6 | | □8 |
| 1.2 Erotic parts of a woman's body (e.g., face, genitals, legs) | □₀ | | \square_{2} | \square_3 | □4 | \square_5 | □6 | | □8 |
| 1.3 Erotic or romantic situations | □₀ | | | □₃ | □ ₄ | | □6 | | □8 |
| 1.4 Caressing, touching, undressing, or foreplay | □₀ | | \square_2 | \square_3 | □₄ | \square_5 | □6 | | □8 |
| 1.5 Sexual intercourse, oral sex, touching to orgasm | □. | | | □₃ | □4 | | □6 | | □8 |
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| Not Done Codelist: 1 Participant refused 2 Clinician un | able to ob | otain 3 | Insufficier | nt time | 4 Instrun | nent failur | e 5 N | ot require | ed |

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Participant's Initials:



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| Center Nur | nber: | Part | ticipant Nu | mber: | | Part | ticipant's l | nitials: _ | st middle last | | |
|--|---------------|--------------------------------|------------------------|---------------|-----------------------|-----------------------|--------------|----------------------|----------------------------|--|--|
| Derogatis Interview for Sexual F | unctio | n (DISF | -SR) (M) | Male Ve | rsion (co | ntinued) | | | | | |
| Section 2—Sexual Arousal SAME AS PAGE 53 DISMALE1 (TYPE 4)PS | | | | | | | | | | | |
| During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences? | Not at all | Less than 1 per month | 1 or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | 1 per day | 2 or 3 per day | 4 or more per day | | |
| 2.1 A full erection upon awakening | □。 | | | | 4 | | □₀ | | □8 | | |
| 2.2 A full erection during a sexual fantasy or daydream | □。 | | | □3 | □4 | | □。 | □7 | □8 | | |
| 2.3 A full erection while looking at a sexually arousing person, movie, or picture | □₀ | | | | 4 | | 6 | | □8 | | |
| 2.4 A full erection during masturbation | □. | | | | a | | □₀ | □, | □₅ | | |
| 2.5 A full erection throughout the phases of a normal sexual response cycle, that is from undressing and foreplay through intercourse and orgasm | □₀ | | | | 4 | | □6 | | | | |

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| Center Num | ber: | Par | ticipant Nu | mber: | | Pa | rticipant's | Initials: | st middle last |
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| Derogatis Interview for Sexual F | unctio | n (DISF | -SR) (M) | Male Ve | rsion (co | ntinued) | | | |
| Section 3—Sexual Behavior/Experiences | SAME | AS PA | AGE 54 | D | ISMA | LE1 (| TYPE | 4)PS | |
| During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities? | Not at all | Less than 1 per month | l or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | 1 per day | 2 or 3 per day | 4 or more per day |
| 3.1 Reading or viewing romantic or erotic books or stories | □, | | | | 4 | | 6 | | 8 |
| 3.2 Masturbation | □. | | | \square_3 | | | □6 | | |
| 3.3 Casual kissing and petting | □, | | | | | | □ ₆ | | □ 8 |
| 3.4 Sexual foreplay | □. | | | | 4 | □₅ | □6 | | □ ₈ |
| 3.5 Sexual intercourse, oral sex, etc. | □. | | | \square_3 | 4 | | □6 | | |
| Section 4—Orgasm | | | | | DIS | MALE | E2 (TY | PE 4) | PS |
| During the past 30 days or since the last time you filled out this inventory, how <u>satisfied</u> have you been with the following? | Not at all | Slightly | Moderately | Highly | Extremely | | | | |
| 4.1 Your ability to have an orgasm | □, | | | | 4 | | | | |
| 4.2 The intensity of your orgasm | □. | | \square_2 | \square_3 | 4 | | | | |
| 4.3 The length or duration of your orgasm | □. | | | \square_3 | 4 | | | | |
| 4.4 The amount of seminal liquid that you ejaculate | □. | | | \square_3 | □₄ | | | | |
| 4.5 Your sense of control (timing) of your orgasm | По | | | | 4 | | | | |
| 4.6 Feeling a sense of relaxation and well-being after orgasm | По | | | | | | | | |
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| Center | Number: | | Participant | Number: | | P | 'articipant's | Initials: | irst middle last |
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| Derogatis Interview for Sexua | ıl Fund | tion (| DISF-SR) (| M) Male \ | ersion (| ontinue | 4) | | |
| Section 5—Drive and Relationship | SA | ME AS | PAGE ! | 55 | DI | SMALE1 (TYPE 4)PS | | | |
| | Not at all | Less than 1 per month | 1 or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | 1 per day | 2 or 3 per day | 4 or more per day |
| 5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse? | □. | | | | □₄ | | □, | | |
| | Not at all | Slightly | Moderately | Highly | Extremely | | | | |
| | | | | | DI | SMAL | .E2 (T` | YPE 4) | PS |
| 5.2 During this period, how interested have you been in sex? | | П | | Пз | □ ₄ | | | | |
| 5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner? | □. | | | □₃ | □₄□ | ISMA | LE3 (T | ΓΥΡΕ 4 | 4)PS |
| | Could not be worse | Very poor | Poor | Somewhat inadequate | Adequate | Above average | Good | Very good | Could not be better |
| 5.4 In general, what would represent the best description of the quality of your sexual functioning? | □。 | | | □3 | □₄ | \square_5 | □6 | | □8 |

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Participant's Initials: first middle last



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| Date completed:day /month /ye | OR Not done → Specify reason (use codelist below): DATEHE | OR (TYPE 4) |
| | | |

Food Cravings Questionnaire—State (FCQ-S)

Below is a list of comments made by people about their eating habits. Please check one answer for each comment that indicates how much you agree with the comment right now, at this very moment. Notice that some questions refer to foods in general while others refer to one or more specific foods. Please respond to each item as honestly as possible.

| | <u>'</u> | | ′ ' F | CQSTA | ATE (T) | <u> (PE 4)PS</u> |
|----|---|----------------------|------------|-------------|-----------|-------------------|
| | SAME AS PAGE 58 | Strongly Disagree | | Nevtral | Agree | Strongly Agree |
| 1 | I have an intense desire to eat [one or more specific foods]. | | | | | |
| 2 | I'm craving [one or more specific foods]. | | | Пз | | |
| 3 | I have an urge for [one or more specific foods] | | | 3 | | 5 |
| 4 | Eating [one or more specific foods] would make things seem just perfect. | | | \square_3 | | |
| 5 | If I were to eat what I am craving, I am sure my mood would improve. | | | □₃ | | |
| 6 | Eating [one or more specific foods] would feel wonderful. | | | □₃ | | |
| 7 | If I ate something, I wouldn't feel so sluggish and lethargic. | | | □₃ | | |
| 8 | Satisfying my craving would make me feel less grouchy and irritable. | | | □₃ | | |
| 9 | I would feel more alert if I could satisfy my craving. | | | 3 | | |
| 10 | If I had [one or more specific foods], I could not stop eating it. | | | □₃ | □₄ | |
| 11 | My desire to eat [one or more specific foods] seems overpowering. | | | 3 | | |
| 12 | I know I'm going to keep on thinking about [one or more specific foods] until I actually have it. | | | □₃ | | |
| 13 | I am hungry. | | | □₃ | | |
| 14 | If I ate right now, my stomach wouldn't feel as empty. | | | □₃ | □₄ | |
| 15 | I feel weak because of not eating. | | | 3 | | |
| N | ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insu | fficient time | 4 Instrume | ent failure | 5 Not rea | uired |

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Participant's Initials:



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| PAGEID = 187 Center No. | umber: Pa | rticipant Number: | | Participant's i | Initials: |
| Date completed:/ | | | | | |
| Food Craving Inventory (FCI-II) | | | | | |
| For each of the foods listed below, please check the | appropriate box. | | С | RAVE (T | YPE 4)PS |
| Note: A craving is defined as an intense desire to co | | | | | |
| Over the past month, how often have you experienced a craving for | Never | Rarely (once or twice) | Sometimes | Often | Always/Almost Every Day |
| 1 Cake SAME AS PAGE 59 | | | □₃ | | |
| 2 Pizza | | | | | |
| 3 Fried chicken | | | | | |
| 4 Gravy | | | | | |
| 5 Sandwich bread | | | | | |
| 6 Sausage | | | | | |
| 7 French fries | | | | | |
| 8 Cinnamon rolls | | | □₃ | | |
| 9 Rice | | | □₃ | | |
| 10 Hot dog | | | □₃ | | |
| 11 Hamburger | | | □₃ | | |
| 12 Biscuits | | | □₃ | | |
| 13 Ice cream | | | □₃ | | |
| 14 Pasta | | | □₃ | | |
| 15 Fried fish | | | □₃ | | |
| 16 Cookies | | | □₃ | \square_{4} | |
| 17 Chocolate | | | □₃ | | |
| 18 Pancakes or waffles | | | □₃ | \Box_4 | |
| 19 Corn bread | | | ₃ | □₄ | |
| 20 Chips | | | \square_3 | \square_{4} | |
| 21 Rolls | | | ₃ | 4 | |
| 22 Cereal | | | ₃ | \square_{4} | |
| 23 Donuts | | | ₃ | | 5 |
| 24 Candy | | | □₃ | \square_{4} | |
| 25 Brownies | | | □₃ | | |
| 26 Bacon | | | □₃ | | |
| 27 Steak | | | \square_3 | | |
| 28 Baked potato | | | □₃ | | |
| Not Done Codelist: 1 Participant refused 2 Clinicia | n unable to obtain | 3 Insufficient tim | ne 4 Instrumer | nt failure 5 N | Not required |

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Participant's Initials: first middle last



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| | ompleted:/ _{month} / | OR Not done → SAME AS | Specify reason (use codelist below PAGE 36 | ÄT EHD R (| TYPE 4) |
| Eati | ng Inventory | | | | |
| 1 | When I smell a sizzling sta difficult to keep from eatin | eak or see a juicy pie ng, even if I have just | ece of meat, I find it very finished a meal. | TFEQA (T) | PE 4)PS |
| 2 | I usually eat too much at | social occasions, like | • | | □₀ False |
| 3 | I am usually so hungry th | at I eat more than th | SAME AS F ree times a day. | True | o False |
| 4 | When I have eaten my que not eating anymore. | ota of calories, I am | usually good about | 1 True | □₀ False |
| 5 | Dieting is so hard for me | because I just get too | hungry. | ☐₁ True | □₀ False |
| 6 | I deliberately take small h | nelpings as a means o | of controlling my weight. | 1 True | o False |
| 7 | Sometimes things just tast I am no longer hungry. | re so good that I keep | on eating even when | □₁ True | □₀ False |
| 8 | Since I am often hungry, I expert would tell me that something more to eat. | | | □₁ True | □₀ False |
| 9 | When I feel anxious, I find | d myself eating. | | ☐₁ True | o False |
| 10 | Life is too short to worry | about dieting. | | , True | o False |
| 11 | Since my weight goes up more than once. | and down, I have go | ne on reducing diets | □₁ True | □₀ False |
| 12 | I often feel so hungry tha | t I just have to eat so | mething. | ☐₁ True | o False |
| 13 | When I am with someone | who is overeating, I | usually overeat too. | ☐₁ True | □₀ False |
| 14 | I have a pretty good idea | of the number of cal | ories in common food. | ☐₁ True | □₀ False |
| 15 | Sometimes when I start e | ating, I just can't seer | m to stop. | ☐₁ True | □₀ False |
| 16 | It is not difficult for me to | leave something on r | my plate. | ☐₁ True | o False |
| 17 | At certain times of the day to eating then. | y, I get hungry becau | se I have gotten used | ☐₁ True | □₀ False |
| 18 | While on a diet, if I eat fo for a period of time to mo | | d, I consciously eat less | ☐₁ True | □₀ False |
| | | | | | |
| Not D | one Codelist: 1 Participant refused | 2 Clinician unable to obta | in 3 Insufficient time 4 Instrume | ent failure 5 N | lot required |

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Participant's Initials: first middle last



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| | Center Number: Participant Number: | _ Participant's Initials: |
|-----|---|-----------------------------------|
| Eat | ing Inventory (continued) | |
| 19 | Being with someone who is eating often makes me hungry to eat also. | ☐₁ True ☐₀ False |
| 20 | SAME AS PAGE 61 When I feel blue, I often overeat. | TFEQA (TYPE 4)PS ☐, True ☐₀ False |
| 21 | I enjoy eating too much to spoil it by counting calories or watching my weight. | ☐₁ True ☐₀ False |
| 22 | When I see a real delicacy, I often get so hungry that I have to eat right away. | ☐₁ True ☐₀ False |
| 23 | I often stop eating when I am not really full as a conscious means of limiting the amount I eat. | ☐, True ☐₀ False |
| 24 | I get so hungry that my stomach often seems like a bottomless pit. | ☐, True ☐₀ False |
| 25 | My weight has hardly changed at all in the last ten years. | ☐₁ True ☐₀ False |
| 26 | I am always hungry so it is hard for me to stop eating before I finish the food on my plate. | ☐₁ True ☐₀ False |
| 27 | When I feel lonely, I console myself by eating. | ☐₁ True ☐₀ False |
| 28 | I consciously hold back at meals in order not to gain weight. | ☐₁ True ☐₀ False |
| 29 | I sometimes get very hungry late in the evening or at night. | ☐₁ True ☐₀ False |
| 30 | I eat anything I want, any time I want. | ☐, True ☐₀ False |
| 31 | Without even thinking about it, I take a long time to eat. | □₁ True □₀ False |
| 32 | I count calories as a conscious means of controlling my weight. | ☐₁ True ☐₀ False |
| 33 | I do not eat some foods because they make me fat. | ☐₁ True ☐₀ False |
| 34 | I am always hungry enough to eat at any time. | ☐₁ True ☐₀ False |
| 35 | I pay a great deal of attention to changes in my figure. | ☐₁ True ☐₀ False |
| 36 | While on a diet, if I eat a food that is not allowed, I often splurge and eat other high calorie foods. | ☐₁ True ☐₀ False |
| | | |

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Participant's Initia

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calerie Phase 2

Month 12 Submission Visit 1

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| | Center Number: | Participant Number: Participant's Initials: |
|------|---|---|
| Eat | ing Inventory (continued) | |
| Plea | se check one answer that is most appropriate to you | I FEUD LITE 31 |
| 37 | How often are you dieting in a conscieNME As effort to control your weight? | SPARFER2 _2 Sometimes _3 Usually _4 Always |
| 38 | Would a weight fluctuation of 5 pounds affect the way you live your life? | \square_1 Rarely \square_2 Sometimes \square_3 Usually \square_4 Always |
| 39 | How often do you feel hungry? | \square_1 Rarely \square_2 Sometimes \square_3 Usually \square_4 Always |
| 40 | Do your feelings of guilt about overeating help you to control your food intake? | ☐₁ Rarely ☐₂ Sometimes ☐₃ Usually ☐₄ Always |
| 41 | How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours? | ☐₁ Easy ☐₂ Slightly difficult ☐₃ Moderately difficult ☐₄ Very difficult |
| 42 | How conscious are you of what you are eating? | ☐₁ Not at all ☐₂ Slightly ☐₃ Moderately ☐₄ Extremely |
| 43 | How frequently do you avoid "stocking up" on tempting foods? | ☐₁ Almost never ☐₂ Seldom ☐₃ Usually ☐₄ Almost always |
| 44 | How likely are you to shop for low calorie foods? | ☐, Unlikely ☐₂ Slightly likely ☐₃ Moderately likely ☐₄ Very likely |
| 45 | Do you eat sensibly in front of others and splurge alone? | □₁ Never □₂ Rarely □₃ Often □₄ Always |
| 46 | How likely are you to consciously eat slowly in order to cut down on how much you eat? | ☐₁ Unlikely ☐₂ Slightly likely ☐₃ Moderately likely ☐₄ Very likely |
| 47 | How frequently do you skip dessert because you are no longer hungry? | ☐₁ Almost never ☐₂ Seldom ☐₃ At least once a week ☐₄ Almost every day |
| 48 | How likely are you to consciously eat less than you want? | ☐, Unlikely ☐, Slightly likely ☐, Moderately likely ☐, Very likely |
| 49 | Do you go on eating binges though you are not hungry? | ☐₁ Never ☐₂ Rarely ☐₃ Sometimes ☐₄ At least once a week |
| 50 | To what extent does this statement describe your eating behavior? "I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow." | ☐₁ Not like me ☐₂ Little like me ☐₃ Pretty good description of me ☐₃ Describes me perfectly |
| 51 | On a scale of 0 to 5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself? | □₀ Eat whatever you want, whenever you want it □₁ Usually eat whatever you want, whenever you want it □₂ Often eat whatever you want, whenever you want it □₃ Often limit food intake, but often "give in" □₄ Usually limit food intake, rarely "give in" □₅ Constantly limiting food intake, never "giving in" |

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Participant's Initials: first middle last

Durham NC 27705



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| Date completed://_ | | → Specify reason (use codelist below |): |
| day month | year S A M I | EAS DAGE 36 DA | TEHDR (TYPE 4) |

Weight Efficacy Lifestyle Questionnaire (WEL)

This form describes some typical eating situations. Everyone has situations which make it very hard for them to keep their weight down. The following are a number of situations relating to eating patterns and attitudes. This form will help you to identify the eating situations which you find the hardest to manage.

Read each situation listed below and decide how confident (or certain) you are that you will be able to resist eating in each of the difficult situations. In other words, pretend that you are in the eating situation right now. On a scale from 0 (not confident) to 9 (very confident), choose ONE number that reflects how confident you feel now about being able to successfully resist the desire to eat. Check this number for each item. SAME AS PAGE 63 WELQ (TYPE 4)PS

| Ιc | I am confident that: | Not confident at all that you can resist the desire to eat | | | | | Very confident that you can resist the desire to eat | | | | | |
|----|---|--|------|------------|-------------|---------------|---|----------------|----------------|----------------|----------------|--|
| | | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | |
| 1 | I can resist eating when I am anxious (nervous). | □₀ | | | \square_3 | _4 | 5 | | | □ ₈ | | |
| 2 | I can control my eating on the weekends. | \square_{o} | | | \square_3 | _4 | \square_5 | □ ₆ | | □8 | | |
| 3 | I can resist eating even when I have to say "no" to others. | □₀ | | | З | 4 | | 6 | | □ * | | |
| 4 | I can resist eating when I feel physically run down. | □₀ | | | \square_3 | \square_{4} | | | | □,8 | | |
| 5 | I can resist eating when I am watching TV. | | | | З | _4 | | 6 | | □ ₈ | | |
| 6 | I can resist eating when I am depressed (or down). | \square_{o} | | | \square_3 | _4 | \square_{5} | □ ₆ | | □,8 | | |
| 7 | I can resist eating when there are many different kinds of food available. | □₀ | | | З | 4 | | | | □, | □ ₉ | |
| 8 | I can resist eating even when I feel it is impolite to refuse a second helping. | | | | Пз | _4 | | | □ ₇ | □, | | |
| 9 | I can resist eating even when I have a headache. | | | | | | | | | 8 | | |
| N | ot Done Codelist: 1 Participant refused 2 Clinician unable | to obta | in 3 | Insufficie | ent time | 4 Ins | trument | failure | 5 Not | require | 4 | |

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials:



PAGEID = 192

| | Center Number: | | Particip | ant Nur | nber: _ | | | Particip | oant's Init | ials: | middle last | | |
|--|-----------------|------------|----------|---------------------------|---------------------|---------------|---------------|--|-------------|----------------|-------------|--|--|
| Weight Efficacy Lifestyle C | Questionnai | re (w | /EL) (co | ntinuec | l) | | | | | | | | |
| SAME AS PAGE | GE 64 | | | nt at a t the d | ll that esire to | eat | | Very confident that you can resist the desire to eat WELQ (TYPE 4)PS | | | | | |
| | | 0 | 1 | 2 | 3 | 4 | VVEL 5 | .Q (1 | 7 7 | 4)PS 8 | 9 | | |
| 10 I can resist eating when I am I | reading. | □₀ | | | Пз | | | □ ₆ | | □ ₈ | □, | | |
| 11 can resist eating when I am (or irritable). | angry | По | | | \square_3 | 4 | | □ ₆ | | □ ₈ | | | |
| 12 I can resist eating even when a party. | l am at | \Box_{o} | | | \square_3 | \square_{4} | \square_{5} | _6 | | □ ₈ | | | |
| 13 I can resist eating even when pressuring me to eat. | others are | □₀ | | | З | | 5 | 6 | | □ ₈ | | | |
| 14 can resist eating when am i | n pain. | □₀ | | | З | | \square_5 | □ ₆ | | □8 | | | |
| 15 I can resist eating just before g | going to | □₀ | | | З | _4 | 5 | | | □ ₈ | | | |
| 16 I can resist eating when I have experienced failure. | e | \Box_{0} | | | З | \square_{4} | \square_{5} | 6 | | □8 | | | |
| 17 I can resist eating when high-care available. | calorie foods | По | | | З | 4 | \square_5 | 6 | | □, | | | |
| 18 I can resist eating even when others will be upset if I don't e | I think eat. | | | | | | | □ ₆ | | □ ₈ | □, | | |
| 19 I can resist eating when I feel uncomfortable. | | | | | З | | | □ ₆ | | | | | |
| 20 I can resist eating when I am I | парру. | | | | \square_3 | 4 | | | | | | | |

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last



| PAGEID = 193 | Number: Participa | nt Numbe | er: | | Partici | pant's Ini | tials: | |
|--|---|--------------|-----------|-------------|------------|---------------|----------------|---------------|
| Date completed:// | SAME AS PAGE 3 OR Not done → Specify | 36 reason | luse code | elist belov | ATEHI | DR (T | YPE | 4) |
| | | | | IV | //AED | S (TY | 'PE 4 |)PS |
| Multiaxial Assessment of Eatin Instructions: Using the scale shown, please rate the | | | | | wor as tri | uthfully | as nossi | ble |
| SAME AS PA | - | Never | Very | Rarely | Some- | Often | Very | Always |
| | | | Rarely | | times | | Often | |
| | | <u></u> □1 | | 3 | <u></u> | <u></u> | 6 | |
| 2 My sleep isn't as good as it used to | be. | | | 3 | 4 | 5 | □ ₆ | |
| 3 I avoid eating for as long as I can. | | | | \square_3 | 4 | 5 | 6 | |
| 4 Certain foods are "forbidden" for m | e to eat. | \square_1 | | \square_3 | | \square_{5} | 6 | \square_{7} |
| 5 I can't keep certain foods in my house binge on them. | because I will | | | | 4 | | □ ₆ | |
| 6 I can easily make myself vomit. | | | | \square_3 | □₄ | \square_5 | 6 | |
| 7 I can feel that being fat is terrible. | | | | 3 | | | 6 | |
| 8 I avoid greasy foods. | | | | \square_3 | | | 6 | |
| 9 It's okay to binge and purge once in | n a while. | | | | | | 6 | |
| 10 I don't eat certain foods. | | | | Пз | | \square_5 | □₀ | |
| 11 I think I am a good person. | | | | | | | □ ₆ | |
| 12 My eating is normal. | | | | \square_3 | □₄ | \square_5 | □。 | |
| 13 I can't seem to concentrate lately. | | | | З | | | 6 | |
| 14 I try to diet by fasting. | | | | \square_3 | | | □₀ | |
| 15 I vomit to control my weight. | | | | З | | | 6 | |
| 16 Lately nothing seems enjoyable any | more. | | | З | □₄ | | 6 | |
| 17 Laxatives help keep you slim. | | | | | | | □ ₆ | |
| 18 I don't eat red meat. | | | | | | | □, | |
| 19 I eat so rapidly I can't even taste my | food. | | | З | | | 6 | |
| Not Done Codelist: 1 Participant refused 2 Clinic | ian unable to obtain 3 In: | sufficient | time 4 | Instrume | nt failure | 5 No | t require | d |

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012



PAGEID = 194

MAEDS (TYPE 4)PS

| | Center Number: Pai | rticipant N | umber: _ | | Pa | rtiapant's | Initials: | irst middle last |
|--|---------------------------------------|-----------------|----------------|-------------|----------------|-------------|---------------|-------------------|
| Multiaxial Asse | ssment of Eating Disorder Sy | mpto | ms (| MAEDS) | (continue | d) | | |
| SAME AS | PAGE 66 | Never | Very Rarely | Rarely | Some- times | Often | Very Often | Always |
| 20 I do everything I | can to avoid being overweight. | | | | | | □。 | |
| 21 When I feel bloat of that feeling. | ed, I must do something to rid myself | | | | | | | |
| 22 I overeat too fre | quently. | | | | | | □6 | |
| 23 It's okay to be o | verweight. | | | \square_3 | □4 | | □6 | |
| 24 Recently I have f | elt that I am a worthless person. | | | Пз | | | 6 | |
| 25 I would be very | upset if I gained 2 pounds. | | | Пз | | | □6 | |
| 26 I crave sweets a | nd carbohydrates. | | | | | 5 | 6 | |
| 27 I lose control wh | en I eat. | | | Пз | | | □6 | |
| 28 Being fat would | be terrible. | | | 3 | | 5 | 6 | |
| 29 I have thought so | eriously about suicide lately. | | | Пз | | | □6 | |
| 30 I don't have any | energy anymore. | | | | | | 6 | |
| 31 eat small portion | ons to control my weight. | | | Пз | | | □6 | |
| 32 l eat 3 meals a c | lay. | | | 3 | | 5 | □6 | |
| 33 Lately I have be | en easily irritated. | | | Пз | | | □6 | |
| 34 Some foods sho | uld be totally avoided. | | | 3 | | 5 | | |
| 35 I use laxatives to | control my weight. | | | Пз | | | 6 | |
| 36 I am terrified by | the thought of being overweight. | | | 3 | | 5 | □₀ | |
| 37 Purging is a goo | d way to lose weight. | | | Пз | | | □, | |
| 38 I avoid fatty foo | ds. | | | | | | □6 | |
| | CALERIE PHASE2 ANNOTATION | √8.0 2 4 | FEB20 | 12 | Pa | rticipant's | Initials: | first middle last |

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Month 12 Submission

MAEDS (TYPE 4)PS

PAGEID = 195

Participant's Initials:

| Center Number: | Participant N | umber: _ | | Pa | rticipant's | Initials: | irst middle last |
|--|---------------|----------------|--------|----------------|-------------|---------------|------------------|
| Multiaxial Assessment of Eating Disorder | Sympto | oms (| MAEDS) | (continue | d) | | |
| SAME AS PAGE 67 | Never | Very Rarely | Rarely | Some- times | Often | Very Often | Always |
| 39 Recently I have felt pretty blue. | | | Пз | □₄ | | 6 | |
| 40 I am obsessed with becoming overweight. | | | Пз | □₄ | | □6 | |
| 41 I don't eat fried foods. | | | Пз | □₄ | | 6 | |
| 42 I skip meals. | | | Пз | □₄ | | □6 | |
| 43 Fat people are unhappy. | | | Пз | □₄ | | 6 | |
| 44 People are too concerned with the way I eat. | | | Пз | □₄ | | □6 | |
| 45 I feel good when I skip meals. | | | 3 | _4 | | 6 | |
| 46 I avoid foods with sugar. | | | _3 | □₄ | | | |
| 47 I hate it when I feel fat. | | | | 4 | | 6 | |
| 48 I am too fat. | | | _3 | | | _6 | |
| 49 I eat until I am completely stuffed. | | | 3 | □₄ | | □, | |
| 50 I hate to eat. | | | 3 | □₄ | | □, | |
| 51 I feel guilty about a lot of things these days. | | | 3 | □₄ | | 6 | |
| 52 I'm very careful of what I eat. | | | _3 | □₄ | | □6 | |
| 53 I can "hold off" and not eat even if I am hungry. | | | Пз | □₄ | | 6 | |
| 54 I eat even when I am not hungry. | | | Пз | □₄ | | □6 | |
| 55 Fat people are disgusting. | | | 3 | □₄ | | 6 | |
| 56 I wouldn't mind gaining a few pounds. | | | 3 | □₄ | | 6 | |

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012



Month 12 Submission V:-:4 T

| | ACEID 406 | | | | | VI | SIT I | | | |
|---|--|------------------|------------|----------------|--------------|---------------|----------------|--|--|--|
| Р | AGEID = 196 Center Number: Participant Number: | Number: _ | | Par | ticipant's l | nitials: | middle last | | | |
| Da | te completed:/OR Not done → Specify re | ason (use | codelist b | | | | | | | |
| | ody Shape Questionnaire (BSQ) | | | | | | | | | |
| We would like to know how you have been feeling about your appearance over the past four weeks BSQ (TYPE 4)PS Please read each question and check the box for the appropriate choice. Please answer all the questions. | | | | | | | | | | |
| Ov | er the Past Four Weeks SAME AS PAGE 68 | Never | Rarely | Some- times | Often | Very Often | Always | | | |
| 1 | Has feeling bored made you brood about your shape? | | | 3 | 4 | | | | | |
| 2 | Have you been so worried about your shape that you have been feeling that you ought to diet? | | | 3 | □₄ | | □ ₆ | | | |
| 3 | Have you thought that your thighs, hips, or bottom are too large for the rest of you? | | | З | | | □6 | | | |
| 4 | Have you been afraid that you might become fat (or fatter)? | | | | | | | | | |
| 5 | Have you worried about your flesh not being firm enough? | | | Пз | | | | | | |
| 6 | Has feeling full (e.g., after eating a large meal) made you feel fat? | | | Пз | □₄ | | | | | |
| 7 | Have you felt so bad about your shape that you have cried? | | | 3 | | | 6 | | | |
| 8 | Have you avoided running because your flesh might wobble? | | | 3 | | | | | | |
| 9 | Has being with thin women/men made you feel self-conscious about your shape? | | | 3 | | | □ ₆ | | | |
| 10 | Have you worried about your thighs spreading out when sitting down? | | | | | | | | | |

Participant's Initials: First middle last CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

2 Clinician unable to obtain

11 Has eating even a small amount of food made you feel

12 Have you noticed the shape of other women/men and felt that your own shape compared unfavorably? 13 Has thinking about your shape interfered with your ability to concentrate (e.g., while watching TV, reading, listening

14 Has being naked, such as when taking a bath, made you

15 Have you avoided wearing clothes which make you particularly aware of the shape of your body? 16 Have you imagined cutting off fleshy areas of your

fat?

to conversations)?

feel fat?

body?

Not Done Codelist: 1 Participant refused

3 Insufficient time

4 Instrument failure

5 Not required



PAGEID = 197

Center Number: ___ Participant Number: _

 $\underset{\text{Participant's Initials:}}{\mathsf{BSQ}} \underbrace{(\mathsf{TYPE}\ 4)}_{\mathit{first}} \underbrace{\mathsf{niddlo}}_{\mathit{last}}$

| Body Shape Questionnaire (BSQ) (continued) | | | | | | |
|--|-------|---------------|----------------|-------|---------------|----------------|
| Over the Past Four Weeks SAME AS PAGE 69 | Never | Rarely | Some- times | Often | Very Often | Always |
| 17 Has eating sweets, cakes or other high calorie food made you feel fat? | | | 3 | | | □6 |
| 18 Have you not gone out on social occasions (e.g., parties) because you have felt bad about your shape? | | | □₃ | □₄ | \square_5 | □6 |
| 19 Have you felt excessively large and rounded? | | | □₃ | 4 | | 6 |
| 20 Have you felt ashamed of your body? | | | □ ₃ | □₄ | \square_5 | |
| 21 Has worry about your shape made you diet? | | | 3 | 4 | | 6 |
| 22 Have you felt happiest about your shape when your stomach has been empty? | | | □₃ | | | |
| 23 Have you thought that you are the shape you are because you lack self-control? | | | Пз | 4 | | □ ₆ |
| 24 Have you worried about other people seeing rolls of flesh around your waist or stomach? | | \square_{2} | □₃ | □₄ | \square_{5} | 6 |
| 25 Have you felt that it is not fair that other women/men are thinner than you? | | | | | | 6 |
| 26 Have you vomited in order to feel thinner? | | \square_{2} | □₃ | | \square_{5} | 6 |
| 27 When in company, have you worried about taking up too much room (e.g., sitting on a sofa or bus seat)? | | | | | | 6 |
| 28 Have you worried about your flesh being dimply? | | \square_{2} | □₃ | □₄ | \square_5 | 6 |
| 29 Has seeing your reflection (e.g., in a mirror or shop window) made you feel bad about your shape? | | | 3 | 4 | | □ ₆ |
| 30 Have you pinched areas of your body to see how much fat is there? | | | \square_3 | □₄ | | |
| 31 Have you avoided situations where people could see your body (e.g., communal changing rooms or swimming pools)? | | | □₃ | | | □ ₆ |
| 32 Have you taken laxatives in order to feel thinner? | □₁ | \square_2 | □₃ | □₄ | \square_{5} | □6 |
| 33 Have you been particularly self-conscious about your shape when in the company of other people? | | | □₃ | | | |
| 34 Has worry about your shape made you feel you ought to exercise? | | | \square_3 | □₄ | | □6 |

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last



PAGEID = 198

| | | Center Number | : Partiapani Num | iber: ran | first middle last | | |
|--|--|------------------|------------------|------------------|-------------------|--|--|
| Handgrip Strength | | | | | | | |
| Date and time of assessment: $\frac{1}{2} - \frac{1}{2} - \frac{1}{2} = \frac{1}{23.59}$ Staff initials: DATEHDR (TYPE 4) OR Not done \rightarrow Specify reason (use codelist below): SAME AS PAGE 4 | | | | | | | |
| 1 D | 1 Dynometer handle position: | | | | | | |
| | Dominant hand (check only one): 1 Left 2 Right 3 Ambidextrous Handgrip strength: SAME AS PAGE 77 HANDGRIP (TYPE 4)PS | | | | | | |
| | Handgrip Strength | Zero Meter Check | Right Hand | Zero Meter Check | Left Hand | | |
| | Test 1—peak force | □₀ | kg | □₀ | kg | | |
| | Test 2—peak force | | kg | | kg | | |
| | Test 3—peak force | По | kg | По | kg | | |
| | | | | | | | |
| | | | | | | | |

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



PAGEID = 199

| | | | Center Number: | Participant 1 | Number: _ | | Particip | oant's Initials: first middle last |
|---|---|-------------|--------------------|--|-----------|-------------|----------|--|
| Isometric/Isokinetic Knee Extension and Flexion | | | | | | | | |
| | ite and time of assessment R Not done → Specify reas | | | | 2 | DATEH | | tials: first middle last |
| 1 Recent injury or pain—right knee? □₀ No □₁ Yes 2 Recent injury or pain—left knee? □₀ No □₁ Yes 3 Specify machine used (PBRC only): □₀ Cybex □₁ Biolex MACHINE <tused></tused> | | | | | | | | |
| | All values corrected | for gravity | y effect torque | Right | Leg | Left l | Leg | If Not Done, Specify Reason (Use codelist below) |
| 3 | 60°/sec knee extension | | peak torque | | N.m | <u> </u> | _ N.m | |
| | | | total work | | N.m | | _ N.m | |
| | | | average power | | watts | | _ watts | |
| 4 | $60^{\circ}/\text{sec}$ knee flexion | | peak torque | | N.m | | _ N.m | |
| | | | total work | | N.m | | _ N.m | |
| | | | average power | | _ watts | 51 S5 S5 | _ watts | |
| 5 | 180°/sec knee extension | | peak torque | 1100 - 101 | N.m | | _ N.m | |
| | | | total work | | N.m | | _ N.m | |
| | | | average power | | _ watts | | _ watts | |
| | | | work fatigue index | | _ % | | _ % | |
| 6 | 180°/sec knee flexion | | peak torque | | N.m | | _ N.m | |
| | | | total work | | N.m | | _ N.m |) — — — — — — — — — — — — — — — — — — — |
| | | | average power | | _ watts | | _ watts | |
| | | | work fatigue index | | _ % | - | _ % | |
| 7 | Isometric knee extension: | trial 1 | peak torque | | N.m | | _ N.m | |
| | | trial 2 | peak torque | | N.m | | _ N.m | u |
| | | trial 3 | peak torque | | _ N.m | | _ N.m | |
| 8 | Isometric knee flexion: | trial 1 | peak torque | - | N.m | | _ N.m | |
| | | trial 2 | peak torque | | N.m | | _ N.m | |
| | | trial 3 | peak torque | | N.m | | _ N.m | |
| | | | | | | | | |

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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



PAGEID = 200

| | Center Number: | Participant Number: | Participant's Initials: |
|---------------------------|---------------------------------------|--------------------------------------|-------------------------------------|
| Clinic Weight | | | |
| 19 107 1000 10 | day / | 00:00 to 23:59 | Staff initials: DATEHDR (TYPE 4) |
| OR Not done → Spec | cify reason (use codelist below): | | DATERIOR (TTT E 4) |
| Clinic weight (if the two | o measurements are more than 0.1 kg o | apart, measure weight a third time): | |
| Weight 1: | kg | SAME AS PAGE 4 | WEIGHT (TYPE 4) |
| | Î | | |
| Weight 2: | kg | | |
| Weight 3: | kg | | |
| Weight of gown: | kg | | |
| Not Done Codelist: 1 | Participant refused 2 Clinician unab | ole to obtain 3 Insufficient time | 4 Instrument failure 5 Not required |

| ca | le | rie |
|----|----|-----|
| | | |

Month 12 Submission Visit 2

| Center Number: | Participant Number: | | Participant's Initials: | first middle | - In or |
|----------------|---------------------|--------|-------------------------|--------------|---------|
| | | PARHDR | (TYPE 4) | TITST MIGGIN | i idst |

| - | al D=20 | | Phase 2 | 2 | | Center N | umber: _ | P | | Number: | 12 Su PARHI | Po | articipant's | s Initials: | is |
|------------------------------|-------------------|--|---|----------------|----------------|---------------------|----------|-------------|-------|---------|------------------|------------|--------------|-------------|-------|
| Tode | ay's date | Day Physical Act | Day | | | | | | | n OR No | ot done → | Specify re | eason (use | codelist be | elow |
| | • | ou employed in the last se Which days (check all that app | • | | ∐₀ No ☐ Mon | → Skip to que | | | | Sat [| l _{Sun} | interv | viewer in | first | t mid |
| | | lays do you consider you | | on-work, days' | | | | _ |] Fri | , – | Sun | | | | |
| | Day of | Date | | p Time I | | Time | | ning (in mi | very | | rnoon (in n | vinutes) | | ning (in m | inute |
| # | Week | | In Bed | Up | Start | Stop | Mod. | Hard | Hard | Mod. | Hard | Hard | Mod. | Hard | 1 |
| 7 (yester- day) | | / | 00:00 to 23:59 : : : : : : : : : | 00:00 to 23:59 | 00:00 to 23:69 | 00:00 to 23:59 | | | | | PARCI | <u> </u> | (PE 4) | PS_ | - - |
| 6 | | / | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | ; 00:00 to 23:59 | | | | | | | | | |
| 5 | | / | 00:00 to 23:59 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | - |
| 4 | | / | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | SAI | ИE AS | PAGE | 71 —— | | | | - |
| 3 | | / | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | ::00:00 to 23:59 | | | | | | | | | - |
| 2 | | / | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | - |
| 1 (1 week ago) | | / | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | . - |



PAGEID = 202

| | | Center Number: | Participant Number: | Participant's Initials: | first middle last |
|----|---|-----------------------------|------------------------------|-------------------------|-------------------|
| S | even-Day Physical Activ | vity Recall (PAR) (co | ontinued) | | |
| 4 | Compared to your physical activity or about the same (check only one)? 1 More 2 Less 3 About the same | • | | CQ (TYPE 4) | |
| In | terviewer: Please answer questions | below and note any com | ments on interview. | | |
| 5 | Were there any problems with the S □₀ No □₁ Yes | Seven-Day PAR interview? | • | | |
| 6 | Do you think this was a valid Seven | n-Day PAR interview? | | | |
| 7 | Were there any activities reported by the second of the s | by the participant that you | u don't know how to classify | • | |



PAGEID = 203

| | | Center Number: | Partic | cipant Number: Particip | icipant's Initials: First middle last | | |
|------------------|--------------------------------------|--------------------------------------|------------------|--|--|--|--|
| 6-D | ay Food Record | | | | | | |
| Com | plete below OR Not done → Specif | y reason (use Codelist b | elow): _ | Staff init | tials: first middle last | | |
| | SAME AS PAGE | 73 | | Replacement Value | | | |
| Day of DLW | Date of Record | Record Quality (check only one) | Day of DLW | FOODRCD (TYPE | Record Quality (check only one) | | |
| 1 | / | 1 Reliable 2 Unreliable 3 Missing | 8 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | | |
| 2 | | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | 9 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | | |
| з | | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | 10 | / | ☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing | | |
| 4 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | 11 | / | 1 Reliable 2 Unreliable 3 Missing | | |
| 5 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | 12 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | | |
| 6 | | 1 Reliable 2 Unreliable 3 Missing | 13 | / | 1 Reliable 2 Unreliable 3 Missing | | |
| | | | | | | | |
| Not l | Done Codelist: 1 Participant refused | 2 Clinician unable to ob | tain 3 | Insufficient time 4 Instrument failure | 5 Not required | | |
| | | | | | | | |



PAGEID = 204

| | | Center Number: | Participant Number: _ | Participant's Initials: first middle last |
|----|--|---|-----------------------|---|
| V | O ₂ Max | | | |
| 1 | Date and time of test:/ | SAME AS PAGE | | DATEHDR (TYPE 4) Staff initials: first middle last |
| | OR Not done → Specify reason (use a | | | VOMAX (TYPE 3) |
| 2 | At what time was the participant's las | st meal/snack eaten? _ | 00:00 to 23:59 | |
| 3 | Rest ECG: Rhythm (check only one): Ventricular conduction (che | \square_1 Sinus | a Atrial fibrillatio | n |
| 4 | Heart rate (HR) data: Resting heart rate Age-predicted library rate (max | heart rate: | bpm | |
| 5 | Reason(s) for termination of testing (c Symptom limited (dyspnea, fatigue) Angina/ischemia → Complete all th Serious arrhythmias (VT or SVT) Changes in blood pressure Ventricular ischemia (schedule stress ii Orthopedic/extremity complaints (pai | mage study, complete ven ins/cramps) | nemic ECG changes oc | rred:bpm OR ₉₆ NA curred:bpm OR ₉₆ NA |
| 6 | Did frequent ventricular ectopy occur □₀ No □₁ Yes → If Yes: When did it occur (c | (e.g., ≥ 7 PVCs/min, bi/tr | | |
| 7 | Peak VO₂: mL/kg/min | L/min | | |
| 9 | Did the participant meet at least 2 of \square_0 No \square_1 Yes \rightarrow If Yes: VO_2 max: Exercise time: $\{minutes}$: $\{seconds}$ | _ | , , , b R | achieve a plateau in VO ₂ (change ≤ 150 mL) between the final two stages ER ≥ 1.1 IR max ± 5 bpm of age-predicted maximum |
| 10 | Blood pressure at VO ₂ peak/VO ₂ ma | x:/ | mm Hg | |
| 11 | Borg RPE score at VO ₂ peak/VO ₂ ma | x: (6-20) | | |
| 12 | ₽ Peak RER: | | | |
| 13 | VE at VO ₂ peak/VO ₂ max: | L/min | | |
| 14 | VE/VO ₂ at VO ₂ peak/VO ₂ max | L/min | | |
| | | | | |

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

5 Not required



Not Done Codelist: 1 Participant refused

Month 12 Submission Visit 3

PAGEID = 205

| | Center Number: Po | rticipant Number: Partici | pant's Initials: first middle las |
|-------------------|--|--|--|
| Core Temp | erature | | |
| Staff Initials | Provide Date of Sample Collection/Procedure | Time of Sample Collection/Procedure | If Not Done, Reason (Use codelist below) |
| | | ADMIT (TYPE 3) | |
| | Start Date: | Start Time | |
| | / | | AS PAGE 87 |
| first middle last | Stop Date: | Stop Time | Ī |
| | / | | |
| Inpatient A | Admission and Discharge | | |
| 1 Inpatient adr | mission date and time:/ | | |
| 2 Inpatient disc | charge date and time:// | 00:00 to 23:59 | |
| | | | |

3 Insufficient time

4 Instrument failure

5 Not required

2 Clinician unable to obtain



PAGEID = 206

| | | | Center Nun | nber: Pa | rticipant Numbe | r: Participant's Initials: | | | | | | |
|---|---|--|---------------|------------------|---------------------------------|----------------------------|------------------|------------------------------|--|--|--|--|
| D | elay | ed-type Hypers | ensitivity (D | тн) | | | | | | | | |
| 1 | Was the DTH worksheet completed? □₀ No □₁ Yes → If Yes: Were any Exclusion criteria met? □₀ No → Proceed with test □₁ Yes → STOP. Do not administer test. | | | | | | | | | | | |
| 2 | Date of injection:/OR Not done → Specify reason (use codelist below): | | | | | | | | | | | |
| 3 | Injection by (initials): first middle lost SAME AS PAGE 85 | | | | | | | | | | | |
| 4 | Arm injected: □1 Right □2 Left | | | | | | | | | | | |
| 5 | DTH results: Note: For each reaction, measure two diameters in millimeters (mm). The first diameter is called the maximum diameter because the induration may not be in the shape of a circle. If the induration is an oval shape, first measure the long diameter and then the diameter perpendicular to it. Do not measure erythema. Reaction is considered positive if the average diameter is equal to or greater than 5 mm. A = Largest diameter DTHADM2 (TYPE 4)PS B = Second diameter perpendicular to A | | | | | | | | | | | |
| | | Antigon | 24 | Hour (@ Visit 4) | | 48 | Hour (@ Visit 5) | | | | | |
| | | Antigen | A (diameter) | B (diameter) | Read By: | A (diameter) | B (diameter) | Read By: | | | | |
| | 1 | Normal saline | mm | mm | | mm | mm | | | | | |
| | 2 | Tetanus toxoid (TT) (check only one): | mm | mm | | mm | mm | | | | | |
| | 3 | Candida (check only one): | mm | mm | first middle last (initials) | mm | mm | first middle test (initials) | | | | |
| | 4 | Trichophyton (check only one): 1 Trichophyton Allergic Extract (AllerMed) 98 Other: Lot #: | mm | mm | | mm | mm | | | | | |

5 Not required

nt failure

Not Done Codelist: 1 Particip



PAGEID = 207

| | Center Number: | Participant Number: | Particip | pant's Initials: | | | | | | | |
|---|------------------------------------|--------------------------------------|--|-------------------|--|--|--|--|--|--|--|
| Clinic Weight | | | | | | | | | | | |
| Weight date and time: | / | ; | Staff ini | tials: | | | | | | | |
| | reason (use codelist below): | 00:00 to 23:59 | DATEHDR | R (TYPE 4) | | | | | | | |
| Clinic weight (if the two m | easurements are more than 0.1 kg a | part, measure weight a third tim | ne): | | | | | | | | |
| Weight 1: | kg | SAME AS PAGE 4 | WEIGHT (| WEIGHT (TYPE 4) | | | | | | | |
| Weight 2: | kg | | | | | | | | | | |
| Weight 3: | 3: MOVED RMR PANEL TO PAGE 207A | | | | | | | | | | |
| Weight of gown: | kg | | | | | | | | | | |
| Outcomes Labs | | | | | | | | | | | |
| Date and time of last meal:/ | | | | | | | | | | | |
| Date and time sample collection started: day month year 00.00 to 23:59 OUTCMELB (TYPE 4)PS | | | | | | | | | | | |
| | Sample | Sample Complete? | If Not Done, Reason (Use codelist below) | Staff Initials | | | | | | | |
| Са | techolamines | □ ₀ No □ ₁ Yes | | first middle last | | | | | | | |
| | Blood | □ ₀ No □ ₁ Yes | | | | | | | | | |
| Oral glucos | e tolerance test (OGTT) | □ ₀ No □ ₁ Yes | | first middle last | | | | | | | |
| If a sample is not obtained, | indicate with a Not Done. | · | | | | | | | | | |
| 24-hour Urine (| Collection | | | | | | | | | | |
| Total Volume | Date of | Time of | If Not Don Reason | Staff Initials | | | | | | | |
| Collected | Sample Collection | Sample Collection | (Use codelist b | elow) | | | | | | | |
| | Start Date: | Start Time: | ` | PAGE 90 | | | | | | | |
| | / | : :: : 23.59 | OAIVIE AO | TAGE 30 | | | | | | | |
| mL | Stop Date: | Stop Time: | | first middle last | | | | | | | |
| | / | :::: | | | | | | | | | |
| | CALERIE PHASE2 ANN | OTATION V8.0.24FFR | 2012 | | | | | | | | |
| Not Done Codelist: 1 Pa | rticipant retused 2 Clinician unab | | | 5 Not required | | | | | | | |



PAGEID = 207A

Layout of data entry screen has changes also

| AGEID = 207A | Center | Number: Participant Number | | Participant's Initio | first middle last | | | | | |
|---|-------------|--|-------------------------------------|--|-------------------|--|--|--|--|--|
| Sex Hormone | | | | | | | | | | |
| If Not Done → Specify reason (use code | list below) | DATEHDR (TYPE 4) | | | | | | | | |
| Contraception method (females only): | | □ None OR Check all that apply: OUTCME2 (TYPE 4) | | | | | | | | |
| CAME AS DAGE |) | ☐ Oral contraceptive → Specify: | | | | | | | | |
| SAME AS PAGE 9 | JUA | ☐ Other → Specify (e.g., barrier, IUD): | | | | | | | | |
| Day 1 | | Date | Time | If Not Done, Reason (use codelist) | Staff Initials | | | | | |
| Day 1 of menses (females enly) | | | | | | | | | | |
| Date and time of last meal (males only | r) | | 00:00 to 23:59 | | | | | | | |
| Hormone level blood draw 1 (males o | nly) | / | 00:00 to 23:59 | | first middle fast | | | | | |
| Hormone level blood draw 2 (fomales of Progesterone level | only) | | | | | | | | | |
| Day 2 | | Date | Time | If Not Done, Reason (use codelist) | Staff Initials | | | | | |
| Date and time of last meal | | | | | | | | | | |
| Hormone level blood draw 3 (females of Progesterone level | only) | | | | | | | | | |
| Metabolic Rate | | | | | | | | | | |
| Sample | | Date of Collection | If Not Done, Re (Use codelist be | low) | f Initials | | | | | |
| Resting Metabolic Rate (RMR)—Visit 4 | - 0 | / | , | YPE 4)PS S PAGE 153 | middle last | | | | | |
| Cart ID | | -003 (623-002) | | PBRC-016 (623- PBRC-017 (623- | • | | | | | |
| Not Done Codelist: 1 Participant refused | 2 Clinic | cian unable to obtain 3 Insufficient ti | me 4 Instrument | failure 5 Not i | required | | | | | |

CRF, page 208

3

| calerie | Phase 2 |
|---------|---------|
|---------|---------|

Month 12 Submission

| | PAGE | EID = 208 | | | Center Nu | mber: _ | P | articipant I | Number: _ | PAF | RHDR | rticipant's (TYPE | Initials: | st middle last | |
|------------------------------|---|------------------------------------|---------------------------------------|----------------|----------------|----------------|------|--------------|--------------|--------|-------------|----------------------|----------------------|----------------|--------------|
| Se | ven-l | Day Physical Activ | vity Reca | (PAR) | | | | | | | | | | | |
| Tod | Today's date:/ | | | | | | | | | | | | | | |
| | Were you employed in the last seven days? | | | | | → Skip to que | | | | | | Interv | iewer ini | tials: | middle last |
| 2 | If Yes: V | Which days (check all that apply)? | ? | | Mon | Tues | Wed | Thurs | Fri _ | Sat _ | Sun | | | | |
| 3 | | | | | | | | | | | | | | | |
| Day | Day of | | Slee | p Time | Work | Time | Mor | ning (in m | | After | noon (in n | | Evening (in minutes) | | |
| # | Week | Date | In Bed | Up | Start | Stop | Mod. | Hard | Very Hard | Mod. | Hard | Very Hard | Mod. | Hard | Very Hard |
| 7 (yester- day) | | day | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | <u>PA</u> F | RCHT | (TYPE | 4)PS | |
| 6 | | | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
| 5 | | / | 00:00 to 23:59 : 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
| 4 | | | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | SAME . | AS PAG | E 71 | | | | |

1 00:00 to 23:59 00:00 to 23:59 week 00:00 to 23:59 00:00 to 23:59 ago) 00:00 to 23:59 00:00 to 23:59

00:00 to 23:59

00:00 to 23:59

00:00 to 23:59

00:00 to 23:59

00:00 to 23:59

00:00 to 23:59

00:00 to 23:59

00:00 to 23:59

year

00:00 to 23:59

00:00 to 23:59

00:00 to 23:59

00:00 to 23:59



PAGEID = 209

| | Center Number: Farnaponi Number: Farnaponi's Initials: first_middle_los |
|----|---|
| S | even-Day Physical Activity Recall (PAR) (continued) |
| 4 | or about the same (check only one)? PARQ (TYPE 4) And the same (check only one)? SAME AS PAGE 72 |
| In | a About the same Iterviewer: Please answer questions below and note any comments on interview. |
| 5 | Were there any problems with the Seven-Day PAR interview? |
| 6 | Do you think this was a valid Seven-Day PAR interview? No |
| 7 | Were there any activities reported by the participant that you don't know how to classify? \Box_0 No \Box_1 Yes |



Participant's Initials: _

PAGEID = 210

| Biopsy Labs | <u> </u> | | | | | | | |
|---------------|--------------------|--|-------------------|--|--|--|--|--|
| Sample | Date of Collection | If Not Done, Reason (Use codelist below) | Staff Initials | | | | | |
| Muscle biopsy | / | | first middle last | | | | | |
| Fat biopsy | | | first middle last | | | | | |

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

SAME AS PAGE 90

BIOPSY (TYPE 4)



Month 18 Submission Month 17 Visit

PAGEID = 211

| | • | Partiapant's Initials | first middle last |
|---|--|--|--------------------------------|
| Clinic Weight | | | |
| Weight date and time: | | Staff initials: | iddle leet |
| | | TEHDR (TYPE | |
| Clinic weight (if the two i | measurements are more than 0.1 kg apart, measure weight a third time): SAME AS PAGE 4 | | |
| Weight 1: | kg | | 4. |
| Weight 2: | kg | EIGHT (TYPE 4 | 4) |
| Weight 3: | kg | | |
| Weight of gown: | kg | | |
| Pregnancy Tes | it control of the con | | |
| □ ₀ No □ ₁ Yes → If Yes: Do | rate urine pregnancy test performed:/ | ST (TYPE 4) | |
| Outcomes Lab | SA | ME AS PAGE 33 | |
| Date and time sample o | collection started:/ | CMELB (TYPE | 4)PS |
| Sample If a sample is not obtained, indicate with a Not Done. | Sample Complete? | If Not Done, Reason (Use codelist below) | Staff Initials |
| Blood | □₀ No □₁ Yes SAME AS PAGI | | 1 |
| | SAIVIL AS FAGI | 02 | first middle last |
| NOTE: B | Vaccine Administration efore any vaccine is administered, review the vaccine questionnaire and protocol for participant eligibility. | If Not Done, | Staff 9 Unitials |
| Vaccine(s) given (check all that apply): | Vaccine Administration infore any vaccine is administered, review the vaccine questionnaire and protocol for participant eligibility. Heppiis Ayecheck one: 1 Havrix (GSK) HEPVAC <tuhvac> 2 Vaqta (Merck) 1008 Other: HEPSPEC V:30 Dose (check one): 1 Adult 1 Pediatric HEPDOSe</tuhvac> | If Not Done, SAME PRS PAGE (Use codelist below) | Staff |
| Vaccine(s) given | Vaccine Administration The province of the content of the conten | If Not Done, SAME PROPAGE (Use codelist below) TUHDOS> C <tutvac></tutvac> | Staff |
| Vaccine(s) given (check all that apply): TD <xye< td=""><td>Vaccine Administration is fore any vaccine is administered, review the vaccine questionnaire and protocol for participant eligibility. Hepthis Ayesheck one: ☐1 Havrix (GSK) HEPVAC<tuhvac> ☐2 Vaqta (Merck) ☐98 Other: HEPSPEC V:30 Dose (check one): ☐1 Adult ☐2 Pediatric HEPDOS ☐ ☐ Tetanus/diphtheria → Check one: ☐1 Decovac (Sanofi-Pasteur) TETVA ☐98 Other:TETSPEC V:30 ☐ ☐ Lot #:TETLOT V:20 ☐ Pneumococcal vaccine → Check one: ☐1 Pneumovax (Merck) PNEUN ☐98 Other:PNEUSPEC</tuhvac></td><td>If Not Done, SAME AS PAGE (Use codelist below) TUHDOS> C<tutvac></tutvac></td><td>Staff ⁹Initials</td></xye<> | Vaccine Administration is fore any vaccine is administered, review the vaccine questionnaire and protocol for participant eligibility. Hepthis Ayesheck one: ☐1 Havrix (GSK) HEPVAC <tuhvac> ☐2 Vaqta (Merck) ☐98 Other: HEPSPEC V:30 Dose (check one): ☐1 Adult ☐2 Pediatric HEPDOS ☐ ☐ Tetanus/diphtheria → Check one: ☐1 Decovac (Sanofi-Pasteur) TETVA ☐98 Other:TETSPEC V:30 ☐ ☐ Lot #:TETLOT V:20 ☐ Pneumococcal vaccine → Check one: ☐1 Pneumovax (Merck) PNEUN ☐98 Other:PNEUSPEC</tuhvac> | If Not Done, SAME AS PAGE (Use codelist below) TUHDOS> C <tutvac></tutvac> | Staff ⁹ Initials |



Month 18 Submission CR Visit 1/Control Visit

PAGEID = 212

| | | Center Number: | Participant Number: | Participant's Initials: first middle last |
|-----|--|------------------------------|---|---|
| C | linic Weight | | | |
| W | eight date and time:/ | | · · · · · · · · · · · · · · · · · · · | Staff initials: |
| | R Not done → Specify reason (use | | | ATEHDR (TYPE 4) |
| Cli | nic weight (if the first two measurem | ents are more than 0.1 kg ap | part, measure weight a third time): | |
| W | eight 1: | _ . kg | SAME AS PAGE 4 | |
| W | eight 2: | kg | V | /EIGHT (TYPE 4) |
| W | eight 3: | kg | | |
| W | eight of gown: | _ • kg | | |
| V | ital Signs | | | |
| As | sessment date and time:/ | | 00:00 to 23:59 | |
| | If waist measurement not done | → Specify reason (use codel | ist below): | VITALS (TYPE 3) |
| 1 | Natural waist measurement (if the first two measurements are more | than 1.0 cm apart, measure n | atural waist circumference a third time): | Staff initials: First middle last |
| | Natural waist measurement 1: | ·_ | SAME AS PAG | GE 29 |
| | Natural waist measurement 2: | · | cm | |
| | Natural waist measurement 3: | ·_ | cm | |
| 2 | Umbilical point waist measureme umbilical point waist circumference a t | | s are more than 1.0 cm apart, measure | |
| | Umbilical point waist measurem | ent 1: | cm | |
| | Umbilical point waist measurem | ent 2: | cm | |
| | Umbilical point waist measurem | ent 3: | cm | |
| 3 | Pulse: bpm OR No | ot done → Specify reason | (use codelist below): | Staff initials: first middle lost |
| 4 | Temperature: | °C OR Not done → Speci | fy 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): | | m | Staff initials: first middle last |
| | 6a Blood pressure 1: | _/ mm Hg Time | e:: OR Not done | → ason (use codelist below): |
| | 6b Blood pressure 2: | _/ mm Hg Time | e:: :: _ | |
| | 6c Blood pressure 3: | _/ mm Hg Time | 9:::: | |
| No | ot Done Codelist: 1 Participant refu | sed 2 Clinician unable to | obtain 3 Insufficient time 4 Inst | rument failure 5 Not required |



Month 18 Submission CR Visit 1/Control Visit

PAGEID = 213

| Center | Number: | Participant N | Number: _ | Par | ticipant's Initia | first middle last |
|--|--|---|--------------|---|-------------------|-------------------|
| 12-Lead ECG | | | | | | |
| Date and Time | | | Findin | 95 ECG (TYP | E 4) | taff Initials |
| DATEHDR (TYPE 4) ——————————————————————————————————— | □ ₁ No □ ₂ Abr | Is ECG (check only one): \begin{align*} \sqrt{1} \text{ Normal} \\ \sqrt{2} Abnormal, not clinically significant (specify): | | | | first middle last |
| Date and time of last meal: | | | | | | |
| Date and time of sample collection:/ | Date and time of sample collection:/ | | | | | |
| Sample | Sample | Complete? | | Done, Reason codelist below) | Staff I | nitials |
| Blood | □₀ No □₁ Yes | | | SAME | AS PAGE | |
| Urine | □₀ No □₁ Yes | | | | first mic | lidle Tast |
| Outcomes Labs | | | | | | |
| Date and time of last meal: | // | year | 00:00 to 23: | | B (TYPE | ∃ 4)PS |
| | // month | | 00:00 to 23: | | S PAGE 1 | |
| Sample | | Sample Com | plete? | If Not Done, Reason (Use codelist belov | | f Initials |
| Blood | | □ ₀ No □ ₁ Yes | | | first | middle last |
| If a sample is not obtained, indicate with a Not Done. | If a sample is not obtained, indicate with a Not Done. | | | | | |

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

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



Month 18 Submission CR Visit 1

PAGEID = 214

| | | Center Number: | Participant Number: Participant's Initials: first middle last | | | | |
|----|---|--------------------------------------|---|--|--|--|--|
| D | oubly Labeled V | Vater (DLW) | | | | | |
| 1 | Date and time of DLW d | osing:/ _{month} / | DLWHDR (TYPE 4) | | | | |
| | OR Not done \rightarrow Specify | reason (use codelist below): _ | | | | | |
| 2 | DLW dose mixture ID an | d bottle number: | CA | | | | |
| 3 | Exact weight of DLW mix | kture:(| SAME AS PAGE 114 grams | | | | |
| 4 | Urine samples: | | DLWCHT (TYPE 4)PS | | | | |
| | Collection | Sample | Date and Time Collected | | | | |
| | Pre dosing (PD) | PDa | / | | | | |
| | | PDb | / | | | | |
| | Day 0 (Visit 1) | DOa | / | | | | |
| | | DOb | / | | | | |
| | Day 7 (Visit 2) | D7a | / | | | | |
| | | D7b | / | | | | |
| | Day 14 (Visit 4) | D14a | / | | | | |
| | | D14b | / | | | | |
| 5 | 5 Affix CRF page label(s) corresponding to this urine sample set: Affix Test Sample Label Here Label Here | | | | | | |
| No | t Done Codelist: 1 Particip | pant refused 2 Clinician unal | ble to obtain 3 Insufficient time 4 Instrument failure 5 Not required | | | | |



Month 18 Submission CR Visit 1

PAGEID = 215

| | Center Number: | Participant Number: | Participant's Initials: | e last | | |
|---|--|----------------------------------|-------------------------|--------|--|--|
| Pregnancy Test | | | | | | |
| Complete only for females. | | PREGTEST (TYPE 4) | | | | |
| Does participant have reproductive □0 No □1 Yes → If Yes: Date urine pregna Results: □1 Negat | ncy test performed: | /SAN | ME AS PAGE 33 | | | |
| DXA Scan | | | | | | |
| 1 Has the participant taken a calcium supplement today? DXASCAN (TYPE 4) | | | | | | |
| \square_0 No \square_1 Yes \rightarrow If Yes: Proceed | with scan and document in | n the Subject Scan Log to infor | n the QA Center. | | | |
| 2 Were any studies involving barium of | or radioisotopes performed | I within 4 weeks prior to the so | heduled DXA exam? | | | |
| □ ₀ No □ ₁ Yes | | SAME AS PAGE 35 | | | | |
| DXA Scan | | DXA Rescan OR | | | | |
| Date of scan:/ | ar | Date of rescan:/ | onth year | | | |
| Area Scanned Check all that apply | If Not Done, Reason (Use codelist below) | | Scanned I that apply | | | |
| ☐ Whole body | | ☐ Whole bo | ody | | | |
| | | | | | | |
| ☐ Forearm | | Forearm | | | | |
| Forearm Spine | | ☐ Forearm | | | | |
| | | | | | | |
| Spine | | Spine | | | | |



Month 18 Submission CR Visit 2

PAGEID = 216

| Center | Number: Participant Number: | Participant's Initials: iniddle last | | | | | |
|---|---|--|--|--|--|--|--|
| Clinic Weight | | | | | | | |
| Weight date and time:/ _{month} / | gr 0000 to 23:59 | Staff initials: | | | | | |
| OR Not done → Specify reason (use Codelist belo | | DATEHDR (TYPE 4) | | | | | |
| Clinic weight (if the first two measurements are more Weight 1: kg | than 0.1 kg apart, measure weight a third time): SAME AS PAGE 4 | : | | | | | |
| Weight 2:kg | | WEIGHT (TYPE 4) | | | | | |
| Weight 3:kg | | | | | | | |
| Weight of gown: kg | | | | | | | |
| Contraception | | | | | | | |
| If Not Done → Specify reason (use codelist below) |): | | | | | | |
| Contraception method (females only): SAME AS PAGE 95 | _ | ify: ord on Concomitant Medications page rier, IUD): | | | | | |
| Not Done Codelist: 1 Participant refused 2 Clinic | Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required | | | | | | |

calerie Phase 2

Month 18 Submission CR Visit 2

| AGEI | D = 217 | | | | Center Nu | ımber: | Po | articipant l | Number: _ | | Po | rticipant's | Initials: | rst middle las |
|-------------|--|------------------------------------|--|--|--|---|---|---|---------------------------------------|---|---|---------------------------------------|---|--|
| /en-D | Day Physical Activ | rity Reca | ll (PAR) | | | | | | | | | | | |
| y's date | e:/ | Day | (check only one): | Mon Tu | es Wed | Thurs | Fri S | at Su | n OR No | t done → | Specify re | eason (use | codelist bei | low): |
| | | | | ∏ _a No | → Skip to au | estion 3 | □. Yes | | | | Interv | iewer ini | tials: | middle last |
| f Yes: W | hich days (check all that apply)? | ? | | Mon | Tues | Wed _ | Thurs | Fri _ | Sat _ | PARE | IDR (I | YPE 4 | .) | |
| Vhich d | ays do you consider your w | | | ? Mon | Tues | Wed | Thurs | Fri _ | Sat | Sun | | | | |
| Day of | Date | · | | | | | | | | | | | | very |
| Week | | In Bed | Up | Start | Stop | Mod. | Hard | Hard | Mod. | Hard | Hard | Mod. | Hard | Hard |
| | , , | 00:00 to 23:59 | :: 00:00 to 23:59 | | | | | | | | | | | |
| | day month year | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | PAR | CHT | TYPE | 4)PS | | |
| | , , | 00:00 to 23:59 | :: 00:00 to 23:59 | | | | | | | | | | | |
| | day month year | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
| | , , | 00:00 to 23:59 | :: | | | | | | | | | | | |
| | day month year | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
| | | : | : | | | SAME | AS PAG | E 71 | | | | | | |
| | day month year | : | : | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
| | | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | | | |
| | day month year | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
| | | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | | | |
| | // | 00:00 to 23:59 | 00:00 to 23:59 | :: | : | | | | | | | | | |
| | day month year | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
| | , , | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | | | |
| | day month year | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
|) ^ f | en-L y's date /ere yo Yes: W /hich d | en-Day Physical Active y's date:/ | en-Day Physical Activity Reca y's date: / | Ven-Day Physical Activity Recall (PAR) V's date: / Day (check only one): Vere you employed in the last seven days? Yes: Which days (check all that apply)? Vhich days do you consider your weekend, or non-work, days' Date Date | ## Company Physical Activity Recall (PAR) ## Company Physical Activ | ren-Day Physical Activity Recall (PAR) y's date: | ## Cen-Day Physical Activity Recall (PAR) ## Control of the Control of Cont | Page Cen-Day Physical Activity Recall PAR | Physical Activity Recall (PAR) Yes | Cen-Day Physical Activity Recall (PAR) Page | Pere you employed in the last seven days? | Part Physical Activity Recall PAR | Physical Activity Recall (PAR) Physical Activity Recall (PAR) | Company Comp |



Month 18 Submission CR Visit 2

PAGEID = 218

| | Center Number: Participant Number: Participant's Initials: |
|----|--|
| S | even-Day Physical Activity Recall (PAR) (continued) |
| 4 | Compared to your physical activity over the past three months, was last week's physical activity more, less, or about the same (check only one)? PARQ (TYPE 4) About the same SAME AS PAGE 72 |
| In | terviewer: Please answer questions below and note any comments on interview. |
| 5 | Were there any problems with the Seven-Day PAR interview? |
| 6 | Do you think this was a valid Seven-Day PAR interview? |
| 7 | Were there any activities reported by the participant that you don't know how to classify? \square_0 No \square_1 Yes |



Month 18 Submission CR Visit 2

PAGEID = 219

| | | Center Number: | Partic | cipant Number: Particip | pant's Initials: | | |
|------------------|--------------------------------------|---|------------------|--|--|--|--|
| 6-D | ay Food Record | | | | | | |
| Com | plete below OR Not done → Specif | y reason (use Codelist b | elow): _ | Staff init | rials: First middle last | | |
| | SAME A | S PAGE 73 | | Replacement Values | | | |
| Day of DLW | Date of Record | Record Quality (check only one) | Day of DLW | FOODRCD (TYPE | Record Quality (check only one) | | |
| 1 | / | n Reliable number 2 Unreliable number 3 Missing | 8 | / | ☐ ₁ Reliable ☐ ₂ Unreliable ☐ ₃ Missing | | |
| 2 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | 9 | / | 1 Reliable 2 Unreliable 3 Missing | | |
| 3 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | 10 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | | |
| 4 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | 11 | / | 1 Reliable 2 Unreliable 3 Missing | | |
| 5 | | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | 12 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | | |
| 6 | | n Reliable n Unreliable n Missing | 13 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | | |
| | | | | | | | |
| Not I | Oone Codelist: 1 Participant refused | 2 Clinician unable to ob | tain 3 | Insufficient time 4 Instrument failure | 5 Not required | | |
| | | | | | | | |



Month 18 Submission CR Visit 2/Control Visit

| PA | | |
|----|--|--|
| | | |
| | | |

| PAGEID = 223 | Center Number: | Participa | nt Numbe | er: | | Partici | pant's Ini | tials: | |
|---|------------------------------|-----------|-------------|----------------|-------------|----------------|---------------|----------------|-------------|
| Date completed:/ | SAME AS OR Not done - | | | | | | | first | middle last |
| · | year | | | | N | /AED | S (TY | 'PE 4 |)PS |
| Multiaxial Assessment of | - J | | | | | | | | |
| Instructions: Using the scale shown, plea | ise rate the following items | on a scal | _ | | | | | | |
| | SAME AS PAGE 65 | | Never | Very Rarely | Rarely | Some- times | Often | Very Often | Always |
| 1 Fasting is a good way to lose | e weight. | | | | 3 | | | 6 | 7 |
| 2 My sleep isn't as good as it u | used to be. | | \square_1 | | \square_3 | | \square_5 | □ ₆ | |
| 3 I avoid eating for as long as | I can. | | | | З | | | 6 | 7 |
| 4 Certain foods are "forbidden | " for me to eat. | | | | З | | | 6 | |
| 5 I can't keep certain foods in my binge on them. | y house because I will | | | | | 4 | | 6 | |
| 6 I can easily make myself von | nit. | | | | З | | 5 | 6 | |
| 7 I can feel that being fat is ter | rible. | | | | 3 | 4 | 5 | 6 | |
| 8 I avoid greasy foods. | | | | | Пз | | \square_{5} | □₀ | 7 |
| 9 It's okay to binge and purge | once in a while. | | | | З | | | □₀ | |
| 10 I don't eat certain foods. | | | | | \square_3 | | \square_{5} | | |
| 11 I think I am a good person. | | | | | З | | | 6 | |
| 12 My eating is normal. | | | | | Пз | □₄ | \square_5 | □₀ | |
| 13 I can't seem to concentrate lo | ıtely. | | | | | | | G | |
| 14 I try to diet by fasting. | | | | | Пз | | \square_5 | □₀ | |
| 15 I vomit to control my weight. | | | | | З | | | □ ₆ | |
| 16 Lately nothing seems enjoyal | ole anymore. | | | | Пз | | | □6 | |
| 17 Laxatives help keep you slim | | | | | 3 | | | □6 | |
| 18 I don't eat red meat. | | | | | 3 | | | □6 | |
| 19 I eat so rapidly I can't even t | aste my food. | | | | | | | 6 | |
| Not Done Codelist: 1 Participant refused | 2 Clinician unable to obta | in 3 Ins | sufficient | time 4 | Instrume | nt failure | 5 No | t require | d |

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Month 18 Submission CR Visit 2/Control Visit

| | _ | | |
|-------------|--------|---|---|
| PA | \sim | | 004 |
| $D\Delta I$ | | _ | ・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・・ |
| 1 / \ | - | _ | - 227 |

| | Center Number: | Participant N | umber: _ | | Pa | rticipant's | Initials: | rst middle last |
|--|---------------------------------------|---------------|----------------|-------------|----------------|-------------|----------------|-----------------|
| Multiaxial Assessment of | Eating Disorder | Sympto | oms (| MAEDS) | (continue | d) | | |
| | | Never | Very Rarely | Rarely | Some- times | Often | Very Often | Always |
| 20 I do everything I can to avoid | being overweight. | | | | EDS (| TYPE | 4)PS | |
| 21 When I feel bloated, I must do of that feeling. | something to rid myse E AS PAGE 66 | If | | | | | | |
| 22 I overeat too frequently. | | | | 3 | □₄ | | 6 | |
| 23 It's okay to be overweight. | | | | Пз | | | | |
| 24 Recently I have felt that I am | a worthless person. | | | 3 | | | 6 | |
| 25 I would be very upset if I gain | ned 2 pounds. | | | 3 | □₄ | | 6 | |
| 26 I crave sweets and carbohyd | rates. | | | Пз | □₄ | | □ ₆ | |
| 27 I lose control when I eat. | | | | З | □₄ | | □, | |
| 28 Being fat would be terrible. | | | | 3 | □₄ | | □ ₆ | |
| 29 I have thought seriously abou | ut suicide lately. | | | \square_3 | □₄ | | 6 | |
| 30 I don't have any energy anymo | ore. | | | 3 | □₄ | | □ ₆ | |
| 31 I eat small portions to control | my weight. | | | Пз | □₄ | | □, | |
| 32 I eat 3 meals a day. | | | | 3 | | | 6 | |
| 33 Lately I have been easily irrit | ated. | | | _3 | □₄ | | □, | |
| 34 Some foods should be totally | avoided. | | | \square_3 | | | 6 | |
| 35 I use laxatives to control my | weight. | | | \square_3 | | | 6 | |
| 36 I am terrified by the thought | of being overweight. | | | 3 | □₄ | | 6 | |
| 37 Purging is a good way to lose | e weight. | | | 3 | □₄ | | 6 | |
| 38 I avoid fatty foods. | | | |]3 | | | | |

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Month 18 Submission CR Visit 2/Control Visit

PAGEID = 225

| Center Number: | Participant N | umber: _ | | Pa | rticipant's | Initials: | irst middle last |
|---|---------------|----------------|----------------|----------------|-------------|----------------|------------------|
| Multiaxial Assessment of Eating Disorder | Sympto | ms (| MAEDS) | (continue | d) | | |
| | Never | Very Rarely | Rarely | Some- times | Often | Very Often | Always |
| 39 Recently I have felt pretty blue. | | | 3 | MAE 4 | DS (T □₅ | YPE | 4)PS |
| 40 I am obsessed with becoming overweight. SAME AS PAGE 67 | | | З | □₄ | | □6 | |
| 41 I don't eat fried foods. | | | 3 | □₄ | | □ ₆ | |
| 42 I skip meals. | | | Пз | □₄ | | □6 | |
| 43 Fat people are unhappy. | | | | | 5 | 6 | |
| 44 People are too concerned with the way I eat. | | | З | □₄ | □₅ | □6 | |
| 45 I feel good when I skip meals. | | | \square_3 | □₄ | | 6 | |
| 46 I avoid foods with sugar. | | | Пз | □₄ | | 6 | |
| 47 I hate it when I feel fat. | | | Пз | □₄ | | | |
| 48 I am too fat. | | | Пз | □₄ | | □, | 7 |
| 49 I eat until I am completely stuffed. | | | З | | | | |
| 50 I hate to eat. | | | Пз | □₄ | 5 | □ ₆ | |
| 51 I feel guilty about a lot of things these days. | | | 3 | □₄ | | □ ₆ | |
| 52 I'm very careful of what I eat. | | | □ ₃ | □₄ | | | |
| 53 I can "hold off" and not eat even if I am hungry. | | | Пз | □₄ | | 6 | |
| 54 I eat even when I am not hungry. | | | Пз | □₄ | | | |
| 55 Fat people are disgusting. | | | 3 | □₄ | | | |
| 56 I wouldn't mind gaining a few pounds. | | | Пз | □₄ | | | |

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Month 18 Submission CR Visit 4

PAGEID = 226

| | Center Number: Participant Number | : Рагпар | first middle last |
|--|--|--|--------------------------------|
| Inpatient Admission and | Discharge | | |
| 1 Inpatient admission date and time: | day month year 00.00 to 23 | ADMIT (TYP | ∃ 3) |
| 2 Inpatient discharge date and time: | No Display SINTIALS, CT | STRDT, CTSTPDT, GOVERNMENT G | CTSTRTM, CTND |
| Clinic Weight | | | |
| Weight date and time:/ _{month} | | Staff init | ials: |
| OR Not done → Specify reason (use cod | | | |
| Clinic weight (if the two measurements are | more than 0.1 kg apart, measure weight a third | time): DATEHDR (T | YPE 4) |
| Weight 1: | _kg SAME AS PAGE 4 | WEIGHT (T | YPE 4) |
| Weight 2: | kg | | |
| Weight 3: | kg | | |
| Weight of gown: | kg | | |
| Metabolic Rate | | | |
| Sample | Date of Collection | If Not Done, Reason (Use codelist below) | Staff Initials |
| Resting Metabolic Rate (RMR)—Visit 5 | // | RMR (TYPE 4 | |
| ADD CARTID TO RMR PANE | day month SAME AS PAC | E 153 | first middle last |
| Cart ID | Tufts-003 (623-002) WASH U-001 | (623-003) PBRC-0 | 016 (623-005) 017 (623-001) |
| | | | |
| Not Done Codelist: 1 Participant refused | 2 Clinician unable to obtain 3 Insufficient ti | me 4 Instrument failure | 5 Not required |

CRF, page 227

ago)

calerie Phase 2

Month 18 Submission CR Visit 4

| | PAGEI | D = 227 | | | | Center No | umber: _ | P | articipant l | Number: _ | PAF | RHDR | rticipant's (TYPE | Initials: | rst middle las |
|------------------------------|-----------|-----------------------------------|--|-------------------|---------------------|---------------------|----------|------------|--------------|-----------|------------|--------------|----------------------|--------------|----------------|
| г | | Day Physical Activ | _ | | | | | | | | | | | | |
| Tod | lay's dat | re:/ | Day | (check only one): | Mon Tu | es Wed | Thurs | Fri | Sat Su | n OR No | t done → | Specify re | eason (use | codelist bel | ow): |
| ١ı | Were ye | ou employed in the last seve | en days? | | □₀ No | → Skip to que | estion 3 | 1 Yes | i | | | Interv | iewer ini | tials: | middle last |
| 2 | If Yes: V | Vhich days (check all that apply) | ? | | ☐ Mon | Tues | Wed | Thurs | Fri _ | Sat | Sun | | | | |
| 3 | Which o | days do you consider your v | veekend, or n | on-work, days | ? Mon | Tues | Wed | Thurs | Fri _ | Sat | Sun | | | | |
| Day | Day of | _ | Slee | p Time | Work | c Time | Mor | ning (in m | | After | noon (in n | | Ever | ing (in min | |
| # | Week | Date | In Bed | Up | Start | Stop | Mod. | Hard | Very Hard | Mod. | Hard | Very Hard | Mod. | Hard | Very Hard |
| 7 (yester- day) | | / | 00:00 to 23:59 | 00:00 to 23:59 | : 00:00 to 23:59 | : 00:00 to 23:59 | | | | | _PAF | RCHT | (TYPE | 4)PS | |
| 6 | | / | 00:00 to 23:59 | 00:00 to 23:59 | : 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
| 5 | | / | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
| 4 | | / | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | SAME A | AS PAG | E 71 | | | | |
| 3 | | | 00:00 to 23:59 00:00 to 23:59 | 00:00 to 23:59 | ::: | ::00:00 to 23:59 | | | | | | | | | |
| 2 | | | 00:00 to 23:59 : : : : : : : : : : : : : : : : : : | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
| 1 | | , , | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | | | |

00:00 to 23:59

00:00 to 23:59

00:00 to 23:59



Month 18 Submission CR Visit 4

PAGEID = 228

| | | Center Number: | Participant Number: | Participant's Initials: |
|----|--|---------------------------|------------------------------|--------------------------------------|
| S | even-Day Physical Activ | vity Recall (PAR) | continued) | |
| 4 | Compared to your physical activity or about the same (check only one)? | • | | l activity more, less, PARQ (TYPE 4) |
| In | terviewer: Please answer questions | below and note any co | mments on interview. | |
| 5 | Were there any problems with the \Box_0 No \Box_1 Yes | Seven-Day PAR interviev | v? | |
| 6 | Do you think this was a valid Seven | n-Day PAR interview? | | |
| 7 | Were there any activities reported I \square_0 No \square_1 Yes | by the participant that y | ou don't know how to classil | ·y? |
| | | | | |



Month 24 Submission Month 23 Visit

PAGEID = 229

| | Center Number: Participant Number: | Participant's Initio | first middle last |
|---|---|---|-------------------|
| Clinic Weight | | | |
| Weight date and time: — | / | Staff initials: | middla last |
| | raman (was as delist below). | TEHDR (TYP | |
| Clinic weight (if the two me | asurements are more than 0.1 kg apart, measure weight a third time): | ` | , |
| Weight 1: | kg SAME AS PAGE 4 | | |
| Weight 2: | kg WE | EIGHT (TYPE | 4) |
| Weight 3: | kg | | |
| Weight of gown: | kg | | |
| Pregnancy Test | | | |
| Complete only for fem | ales. | | |
| □ ₀ No | e urine pregnancy test performed:/ | EST (TYPE 4) | |
| | ults: 1 Negative | | |
| Kes | | ME AS PAGE 33 | 3 |
| Outcomes Labs | | | |
| Date and time sample col | lection started:/ | CMELB (TYP | E 4)PS |
| Sample If a sample is not obtained, indicate with a Not Done. | Sample Complete? | If Not Done, Reason (Use codelist below) | Staff Initials |
| Blood | □₀ No □₁ Yes | | first middle last |
| NOTE: Befor | Vaccine Administration e any vaccine is administered, review the vaccine questionnaire and protocol for participant eligibility. | If Not Done, AS RAGEn211 (Use codelist below) | Staff Initials |
| Vaccine(s) given (check all that apply): | ☐ Hepatitis A → Check one: ☐1 Havrix (GSK) ☐2 Vaqta (Merck) ☐98 Other: ☐ Dose (check one): ☐1 Adult ☐2 Pediatric ☐ Lot #: | S <tuhdos></tuhdos> | first middle fost |
| Not Done Codelist: 1 Part | icipant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrur | ment failure 5 Not | required |
| 7,000 | Vaccine Display same as page 211 and N Display: TD PV | | 12002 |

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PAGEID = 230

| | Center Number: Participant Number: | Participant's Initials: |
|-----|--|---|
| Cl | Clinic Weight | |
| w | Weight date and time:/ | Staff initials: first middle last |
| | OR Not done → Specify reason (use Codelist below): | DATEHDR (TYPE 4) |
| Cli | Clinic weight (if the first two measurements are more than 0.1 kg apart, measure weight a thir | d time): |
| w | Weight 1: kg SAME AS PAGE | 4 |
| W | Weight 2:kg | WEIGHT (TYPE 4) |
| W | Weight 3: kg | |
| W | Weight of gown: kg | |
| ٧ | Vital Signs | |
| As | Assessment date and time:// | |
| Г | If waist measurement not done → Specify reason (use codelist below): | VITALS (TYPE 3) |
| ין | Natural waist measurement (if the first two measurements are more than 1.0 cm apart, measure natural waist circumference a | third time): Staff initials: |
| | Natural waist measurement 1: cm SAME | AS PAGE 29 |
| | Natural waist measurement 2: cm | |
| | Natural waist measurement 3: cm | |
| 2 | 2 Umbilical point waist measurement (if the first two measurements are more than 1.0 cm apar umbilical point waist circumference a third time): | t, measure |
| | Umbilical point waist measurement 1: cm | |
| | Umbilical point waist measurement 2: cm | |
| | Umbilical point waist measurement 3: cm | |
| 3 | 3 Pulse: bpm OR Not done → Specify reason (use codelist below): | Staff initials: |
| 4 | 1 Temperature: °C OR Not done → Specify reason (use codelist below): | Staff initials: first middle last |
| 5 | 5 Respirations: per minute OR Not done → Specify reason (use codelist below): | Staff initials: first middle last |
| 6 | 5 Blood pressure (check only one): \square_1 Left arm \square_2 Right arm | Staff initials: first middle last |
| | 6a Blood pressure 1:/ mm Hg Time:: OR N | ot done → pecify reason (use codelist below): |
| | 6b Blood pressure 2:/ mm Hg Time::: | · · · · · · · · · · · · · · · · · · · |
| | 6c Blood pressure 3:/ mm Hg Time::: | |
| No | Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time | 4 Instrument failure 5 Not required |



PAGEID = 231

| Center | Number: Participant | Number: Pa | rticipant's Initials: |
|---|------------------------------|---|--------------------------|
| 12-Lead ECG | | | |
| Date and Time | | Findings ECG (TY | (PE 4) Staff Initials |
| DATEHDR (TYPE 4) | | SAME AS PAGE : Illy significant (specify): significant (specify): | 30 |
| Safety Labs | | | |
| Date and time of last meal: day / | oith year 00:00 to | SAFETY | LB (TYPE 4) |
| Sample | Sample Complete? | If Not Done, Reason (Use codelist below) | Staff Initials |
| Blood | □₀ No □₁ Yes | SAMI | E AS PAGE 30 |
| Urine | □₀ No □₁ Yes | | first middle last |
| Pregnancy Test | | | |
| Complete only for females. Does participant have reproductive potential: □₀ No □₁ Yes → If Yes: Date urine pregnancy test p Results: □₁ Negative □₂ Positive | | PREGTEST SAME A | T (TYPE 4) AS PAGE 33 |
| Not Done Codelist: 1 Participant refused 2 Clinic | ian unable to obtain 3 Insuf | ficient time 4 Instrument fail | ure 5 Not required |



PAGEID = 232

| | | Center Number: | Participant Number: Participant's Initials: |
|----|-----------------------------------|-------------------------------|--|
| D | oubly Labeled V | Vater (DLW) | |
| | | | DLWHDR (TYPE 4) |
| ' | Date and time of DLW d | osing:/ _{month} / | year 00:00 to 23:59 Staff initials: |
| | OR Not done \rightarrow Specify | reason (use codelist below): | _ |
| 2 | DLW dose mixture ID an | d bottle number: | CA |
| 3 | Exact weight of DIW mix | xture: | SAME AS PAGE 114 |
| | Exact weight of DEW hills | | |
| 4 | Urine samples: | | DLWCHT (TYPE 4)PS |
| | Collection | Sample | Date and Time Collected |
| | Pre dosing (PD) | PDa | / |
| | | PDb | / |
| | Day 0 (Visit 1) | DOα | / |
| | | DOP | / |
| | Day 7 (Visit 2) | D7a | / |
| | | D7b | / |
| | Day 14 (Visit 4) | D14a | / |
| | | D14b | / |
| 5 | Affix CRF page label(s) | corresponding to this urine s | ample set: Affix Affix Test Sample Retest Sample |
| | | | Label Here Label Here |
| ١. | . D C. J. P | | No. of the Control of |
| No | t Done Codelist: 1 Particip | oant refused 2 Clinician unal | ble to obtain 3 Insufficient time 4 Instrument failure 5 Not required |

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PAGEID = 233

| | Center Nu | mber: | Participant Nu | mber: Participant's Initials: first middle last | | | |
|--|-------------|-------------|-------------------|---|--|--|--|
| Physical Examination | | | | | | | |
| Date of examination:/ | | | AS PAGE 32 | Staff initials: Time Time Time Time | | | |
| Body System | | Assessments | 1 | If Abnormal or Not Done: Explain | | | |
| body System | Normal | Abnormal | Not Done | " Wallet life of Met Bollet Evhicill | | | |
| General appearance: | | □₀→ | □ ₉₇ → | PEXAM (TYPE 4)PS | | | |
| 2 Head, Ears, Eyes, Nose, Throat: | \Box_1 | □₀→ | □ ₉₇ → | SAME AS PAGE 32 | | | |
| 3 Neck: | | □₀→ | □ ₉₇ → | | | | |
| 4 Heart: | | □₀→ | □ ₉₇ → | | | | |
| 5 Lungs: | \Box_1 | □₀→ | □ ₉₇ → | | | | |
| 6 Abdomen: | \square_1 | □₀→ | □ ₉₇ → | | | | |
| 7 Lymph nodes: | \Box_1 | □₀→ | □ ₉₇ → | | | | |
| 8 Extremities/Skin: | \Box_1 | □₀→ | □ ₉₇ → | | | | |
| 9 Neurological: | \Box_1 | □₀→ | □ ₉₇ → | | | | |
| 10 Musculoskeletal: | | □₀→ | □ ₉₇ → | | | | |
| | Normal | Abnormal | Not Done* | | | | |
| 11 Genitourinary: | | □₀→ | □ ₉₇ → | | | | |
| 12 Breast: | \square_1 | □₀→ | □ ₉₇ → | | | | |
| Physician's Signature | | | | | | | |
| Investigator: | signatu | ire | | Date:/ | | | |
| Not done at this examination OR Referred participant to primary care physician for exam. | | | | | | | |

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

Calerie Phase 2_CRF_V9.0_28 SEP 2010

5 Not required



PAGEID = 234

| | Center Number: | Participant Number: | Participant's Initials: | | | | |
|---|--|------------------------------|--------------------------------|--|--|--|--|
| DXA Scan | | | | | | | |
| Has the participant taken a calcium supplement today? □₀ No □₁ Yes → If Yes: Proceed with scan and document in the Subject Scan Log to inform the QA Center. | | | | | | | |
| Were any studies involving barium or radioisotopes performed within 4 weeks prior to the scheduled DXA exam? SAME AS PAGE 35 | | | | | | | |
| DXA Scan | | DXA Rescan ORNA | | | | | |
| Date of scan:/ | | Date of rescan:/ | | | | | |
| Area Scanned Check all that apply | If Not Done, Reason (Use codelist below) | | a Scanned all that apply | | | | |
| ☐ Whole body | | ☐ Whole | body | | | | |
| Forearm | | Forear | m | | | | |
| Spine | | Spine | | | | | |
| ☐ Hip | | ☐ Hip | | | | | |
| Not Done Codelist: 1 Participant refused | 2 Clinician unable to obtai | n 3 Insufficient time 4 Inst | trument failure 5 Not required | | | | |

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Calerie Phase 2_CRF_V9.0_28 SEP 2010



| AGEID = 241 | Center Number: | Participant Number: | | Participant's Initials: first middle last | | | | | |
|--|--------------------------|--|----------------------|---|-----------------------------|--|--|--|--|
| Date completed:/ | OR Not dor | OR Not done → Specify reason (use codelist SAME AS PAGE 36 | | | below): DATEHDR (TYPE 4) | | | | |
| Profile of Mood States | SAIVIE F | AS PAGE 36 | | JATEHDR (| TYPE 4) | | | | |
| Instructions: Please describe how you feel right now by checking one box for each of the words listed below. | | | | | | | | | |
| Feeling | Not At All | A Little | Moderately | Quite A Bit | FYPE 4)PS Extremely | | | | |
| 1 Friendly | SAME AS PA | GE 42 | | | 4 | | | | |
| 2 Tense | | | | \square_3 | | | | | |
| 3 Angry | | | | | | | | | |
| 4 Worn out | | | | | | | | | |
| 5 Unhappy | | | | 3 | 4 | | | | |
| 6 Clear-headed | \square_{o} | \square_1 | \square_{2} | \square_3 | 4 | | | | |
| 7 Lively | \square_{o} | | | \square_3 | 4 | | | | |
| 8 Confused | \Box_{o} | | \square_{2} | \square_3 | \square_{4} | | | | |
| 9 Sorry for things done | | | | 3 | | | | | |
| 10 Shaky | | | | \square_3 | | | | | |
| 11 Listless | | | | 3 | | | | | |
| 12 Peeved | \square_{o} | \square_1 | \square_{2} | \square_3 | \square_{4} | | | | |
| 13 Considerate | | | | 3 | | | | | |
| 14 Sad | \square_{o} | | | | | | | | |
| 15 Active | По | | | | | | | | |
| 16 On edge | \square_{o} | \square_1 | \square_{2} | \square_3 | | | | | |
| 17 Grouchy | \square_{o} | | | 3 | | | | | |
| 18 Blue | \Box_{o} | | | | | | | | |
| 19 Energetic | | | | | | | | | |
| 20 Panicky | | | | | | | | | |
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| Not Done Codelist: 1 Participant refus | ed 2 Clinician unable to | obtain 3 Insuff | icient time 4 Instru | ment failure 5 N | lot required | | | | |
| | | | | Participant's I | nitials: | | | | |

ırham NC 27705



PAGEID = 242

| | Center Number: _ | Participant N | Participant's I | Participant's Initials: first middle last | | |
|--|-----------------------------|------------------------------|-----------------------------|---|-------------------------|--|
| Profile of Mood States (d | ontinued) | | | | | |
| Feeling | Not At All | A Little | Moderately | Quite A Bit | Extremely | |
| 21 Hopeless | | | | MS (TYPE 4) | PS | |
| 22 Relaxed | □ _o SAM | E AS PAGE 43 | | Пз | | |
| 23 Unworthy | \square_{o} | | | \square_3 | | |
| 24 Spiteful | \square_{o} | \square_1 | \square_{2} | \square_3 | □₄ | |
| 25 Sympathetic | \square_{o} | | | □3 | □4 | |
| 26 Uneasy | \square_{o} | \square_1 | \square_{2} | \square_3 | | |
| 27 Restless | | | | □₃ | 4 | |
| 28 Unable to concentrate | \square_{o} | | \square_{2} | \square_3 | □₄ | |
| 29 Fatigued | \square_{0} | | | \square_3 | \square_4 | |
| 30 Helpful | \Box_{0} | | | Пз | 4 | |
| 31 Annoyed | | | | 3 | | |
| 32 Discouraged | \square_{0} | | | 3 | 4 | |
| 33 Resentful | | | | 3 | 4 | |
| 34 Nervous | | | | \square_3 | 4 | |
| 35 Lonely | | | | 3 | 4 | |
| 36 Miserable | \Box_{0} | | | □ ₃ | 4 | |
| 37 Muddled | | | | 3 | 4 | |
| 38 Cheerful | \square_{0} | | | | 4 | |
| 39 Bitter | | | | 3 | | |
| 40 Exhausted | | | | 3 | 4 | |
| 41 Anxious | | | | \square_3 | | |
| 42 Ready to fight | \square_{0} | | | \square_3 | 4 | |
| 43 Good-natured | | | | \square_3 | _4 | |
| Copyright © 2003, 2005 Maurice Lorr, Ph.D., Douglas M. | McNair Ph.D., and JW P. Heu | chert, Ph.D. under exclusive | license to Multi-Health Sys | tems Inc. All rights reserved. | In the U.S.A., P.O. Box | |

950, North Tonawanda, NY 141200950. In Canada 2770 Victoria Bulk Ava. Touris ON MONTATION V8.0 24FEB2012 icipant's Initials:

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| | Center Number: | Center Number: Participant Number: | | | Participant's Initials: | | | |
|--|--|------------------------------------|------------------------------|-----------------|-------------------------|--|--|--|
| Profile of Mood S | itates (continued) | | | | | | | |
| Feeling | Not At All | A Little | Moderately | Quite A Bit | Extremely | | | |
| 44 Gloomy | | | | MS (TYPE 4) | PS | | | |
| 45 Desperate | □, SA | ME AS PAGE 44 | | 3 | □ ₄ | | | |
| 46 Sluggish | \square_{o} | \square_1 | \square_2 | \square_3 | 4 | | | |
| 47 Rebellious | | □, | | \square_3 | _4 | | | |
| 48 Helpless | \square_{o} | \square_1 | \square_{2} | \square_3 | _4 | | | |
| 49 Weary | | | | \square_3 | 4 | | | |
| 50 Bewildered | \square_{o} | \square_1 | | \square_3 | 4 | | | |
| 51 Alert | | | | 3 | _4 | | | |
| 52 Deceived | \square_{o} | \Box_1 | \square_{2} | \square_3 | 4 | | | |
| 53 Furious | | | | \square_3 | 4 | | | |
| 54 Efficient | \square_{o} | \Box_1 | \square_{2} | \square_3 | | | | |
| 55 Trusting | | | | 3 | 4 | | | |
| 56 Full of pep | \square_{o} | \square_1 | | \square_3 | | | | |
| 57 Bad-tempered | | | | \square_3 | 4 | | | |
| 58 Worthless | \square_{o} | \square_1 | | \square_3 | 4 | | | |
| 59 Forgetful | | | | □₃ | 4 | | | |
| 60 Carefree | \square_{o} | \square_1 | \square_{2} | \square_3 | \square_4 | | | |
| 61 Terrified | | \Box_1 | | \square_3 | 4 | | | |
| 62 Guilty | \square_{o} | \Box_1 | \square_{2} | □₃ | 4 | | | |
| 63 Vigorous | | | | □₃ | 4 | | | |
| 64 Uncertain about th | ings | | | 3 | 4 | | | |
| 65 Bushed | | | | 3 | 4 | | | |
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| CA | LERIE PHASEE2 ANN | OTATION V8.0 | | Participant's I | nitials: middle last | | | |

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| | | Center Number: | Participant Numb | er: | | Participant' | s Initials: | iest midella last | |
|--|---|--|---------------------------|---------------|-----------------|----------------|-----------------|-------------------|--|
| Da | ite completed:/ _{month} / | SAME AS I OR Not done | PAGE 36 Specify reason | (use code | list below): | EHDR | (TYPE | E 4) | |
| P | Perceived Stress Scale (PSS) | | | | | | | | |
| Instructions: The questions in this scale ask you about your feelings and thoughts during the last month. In each case, please indicate how often you felt or thought a certain way. Please check only one answer for each question. PSS (TYPE 4) | | | | | | | | | |
| | | SAME AS PAGE 45 | | Never | Almost Never | Some- times | Fairly Often | Very Often | |
| 1 | In the last month, how often h unable to control the importa | | | | | | | | |
| 2 | In the last month, how often by your ability to handle your pe | | nt about | \square_{o} | \square_1 | \square_{2} | \square_3 | \square_4 | |
| 3 | In the last month, how often h going your way? | nave you felt that thi | ngs were | | | | | | |
| 4 | In the last month, how often h piling up so high that you cou | 5. The state of th | | | | | | 4 | |
| N | Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required | | | | | | | | |

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last



PA

| AGEID = 245 | Center Number: Participant | Number: | Partic | cipant's Initials | first middle last | | | | |
|--|---|---------------------------------|-----------------------------|----------------------------|------------------------------|--|--|--|--|
| Date completed:/ | OR Not done → Specify r SAME AS PAGE 36 | eason (use codeli | ist below): DATEH | ĪDR (TY | PE 4) | | | | |
| Pittsburgh Sleep Quality I | ndex (PSQI) | | | | | | | | |
| Instructions: The following questions re the most accurate reply fo | late to your usual sleep habits durit r the majority of days and nights in | | | | | | | | |
| During the past month | SAME AS PAGE | 46 | PSQI1 | (TYPE | 4) | | | | |
| 1 When have you usually gone | to bed? : : : : : : : : : : : : : : : : : : : | | | | | | | | |
| 2 How long (in minutes) has it to | aken you to fall asleep each | night? | minutes | 5 | | | | | |
| 3 When have you usually gotten up in the morning? | | | | | | | | | |
| 4 How many hours of actual sleep (This may be different than the number of hours | | | | | | | | | |
| 5 During the past month, how a sleeping because you (check | • | Not during the past month | Less than once a week | Once or twice a week | 3 or more times a week | | | | |
| Cannot get to sleep within | 30 minutes | \square_{0} | | | З | | | | |
| b Wake up in the middle of the | ne night or early morning | \square_{\circ} | | | З | | | | |
| • Have to get up to use the b | athroom | \square_{o} | | | \square_3 | | | | |
| d Cannot breathe comfortable | у | \square_{\circ} | | | З | | | | |
| e Cough or snore loudly | | \square_{o} | | | \square_3 | | | | |
| f Feel too cold | | \square_{o} | \square_1 | \square_{2} | З | | | | |
| g Feel too hot | | \square_{o} | | | \square_3 | | | | |
| h Have bad dreams | | \square_{\circ} | | | З | | | | |
| i Have pain | | \square_{\circ} | | | \square_3 | | | | |
| Other reason(s), please de you have had trouble sleep reason(s): | scribe, including how often ing because of this | \square_{o} | | | \square_3 | | | | |
| 6 During the past month, how a medicine (prescribed or "over the cou | | | | | \square_3 | | | | |
| 1989, with permission from Elsevier Science. Not Done Codelist: 1 Participant refused | 2 Clinician unable to obtain 3 Insu | fficient time 4 I | nstrument failure | 5 Not re | quired 1 | | | | |
| | PHASEE2 ANNOTATION V8 | | Partie | cipant's Initials | | | | | |

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Durham NC 27705

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| | Center Number: | Participan | t Number: | Parti | cipant's Initials: | first middle last |
|----|---|---------------|----------------------|----------------------------------|-------------------------------|---------------------------------|
| Pi | ittsburgh Sleep Quality Index (PSQI) | (continued) | | | | |
| | SAME AS PAGE 47 PSC | QI2(TYPE 3) | Never | Once or twice | Once or twice each week | 3 or more times each week |
| 7 | During the past month, how often have you staying awake while driving, eating meals, a social activity? | | | | | |
| | | | No problem at all | Only a very slight problem | Somewhat of a problem | A very big problem |
| 8 | During the past month, how much of a probeen for you to keep up enthusiasm to get | | \square_{\circ} | | | З |
| | | | Very good | Fairly good | Fairly bad | Very bad |
| 9 | During the past month, how would you ra quality overall? | te your sleep | \square_{o} | | | \square_3 |

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last



PAGFID = 247

| GEID = 241 | Center Number: | Participant Number: | Participant's Initials: | first middle | last |
|------------|----------------|---------------------|-------------------------|--------------|------|
| | | | | | |

Date completed: — Journal OR Not done → Specify reason (use codelist below): —DATEHDR (TYPE 4)

Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version

Instruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about sexual fantasies or daydreams, while another inquires about the kinds of sexual experiences that you have. You are also asked about the nature of your sexual arousal and the quality of your orgasm. There are also a few other questions about different areas of your sexual relationship.

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "O = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied."

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best describes your personal experience.

DISFEM1 (TYPE 4)PS

If you have any questions, please ask the person who gave you the inventory for help.

Section 1—Sexual Cognition/Fantasy

SAME AS PAGE 48

| During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about: | Not at all | Less than 1 per month | 1 or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | 1 per day | 2 or 3 per day | 4 or more per day | |
|--|---------------|--------------------------------|------------------------|---------------|-----------------------|-----------------------|--------------|----------------------|----------------------------|--|
| 1.1 A sexually attractive person | | | | 3 | 4 | 5 | | | | |
| 1.2 Erotic parts of a man's body (e.g., face, shoulders, legs) | □₀ | | | \square_3 | _4 | 5 | | | □8 | |
| 1.3 Erotic or romantic situations | □, | | | | 4 | | 6 | | | |
| 1.4 Caressing, touching, undressing, or foreplay | □. | | | Пз | | | | | □8 | |
| 1.5 Sexual intercourse, oral sex, touching to orgasm | □, | | | | 4 | | 6 | | □ ₈ | |
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Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain

3 Insufficient time

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: _____

5 Not required

4 Instrument failure



Participant's Initials: first middle last PAGEID = 248 Center Number: ___ Participant Number: ___ _

| Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued) | | | | | | | | | | | |
|---|---------------|--------------------------------|------------------------|---------------|-----------------------|-----------------------|----------------|----------------------|----------------------------|--|--|
| Section 2—Sexual Arousal SAME AS | PAGE 4 | .9 | | | DIS | SFEM1 | (TYF | PE 4)P | S | | |
| During the past 30 days or since the last time you filled out this inventory, how often did you have the following experiences? | Not at all | Less than 1 per month | 1 or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | 1 per day | 2 or 3 per day | 4 or more per day | | |
| 2.1 Feel sexually aroused while alone | | | | | 4 | | □ ₆ | | □8 | | |
| 2.2 Actively seek sexual satisfaction | □. | | | | | | □6 | | □ ₈ | | |
| 2.3 Feel sexually aroused with a partner | □. | | | | 4 | | 6 | | □8 | | |
| | Never | Rarely | Sometimes | Usually | Always | DISFE | M2 (| ГҮРЕ | 4)PS | | |
| 2.4 Have normal lubrication with masturbation | | | | | | | | | | | |
| 2.5 Have normal lubrication throughout sexual relations | | | | | | | | | | | |

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| Dorogatic Interview for Sexual | | | | | | | | | |
|---|---------------|--------------------------------|------------------------|---------------|-----------------------|-----------------------|----------------|----------------------|----------------------------|
| Derogatis Interview for Sexual Function (DISF-SR) (F) Female Version (continued) | | | | | | | | | |
| Section 3—Sexual Behavior/Experiences | SAM | E AS P | AGE 50 |) | DIS | SFEM [®] | 1 (TYF | PE 4)F | PS |
| During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities? | Not at all | Less than 1 per month | 1 or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | 1 per day | 2 or 3 per day | 4 or more per day |
| 3.1 Reading or viewing romantic or erotic books or stories | □, | | | | 4 | ₅ | □6 | | □ ₈ |
| 3.2 Masturbation | | | | Пз | □4 | \square_5 | □6 | □7 | □8 |
| 3.3 Casual kissing and petting | | | | | | ₅ | □ ₆ | □ ₇ | □8 |
| 3.4 Sexual foreplay | □, | | | \square_3 | □4 | □ ₅ | □ ₆ | □7 | □8 |
| 3.5 Sexual intercourse, oral sex, etc. | □. | | | \square_3 | | | □6 | | □8 |
| Section 4—Orgasm | | | | | DIS | SFEM: | 3 (TYF | PE 4)F | PS |
| During the past 30 days or since the last time you filled out this inventory, how satisfied have you been with the following? | Not at all | Slightly | Moderately | Highly | Extremely | | | | |
| 4.1 Your ability to have an orgasm | | | | | | | | | |
| 4.2 The intensity of your orgasm | | | | Пз | □₄ | | | | |
| 4.3 The ability to have multiple orgasms (if typical for you) | | | | | | | | | |
| 4.4 Feelings of closeness and togetherness with your partner | □. | | | \square_3 | □4 | | | | |
| 4.5 Your sense of control (timing) of your orgasm | | | | | | | | | |
| 4.6 Feeling a sense of relaxation and well-being after orgasm Copyright © 1987 by Leonard R. Derogatis PhD | □₀ | | | Пз | □4 | | | | |

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Participant's Initials: first middle last



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| Center | Number: | | Participant | Number: | | P | articipant's | s Initials: | irst middle last |
|--|--------------------------|--------------------------------|------------------------|------------------------|-----------------------|-----------------------|----------------|----------------------|----------------------------|
| Derogatis Interview for Sexua | l Fund | tion (| DISF-SR) (| F) Female | Version | (continue | ed) | | |
| Section 5—Drive and Relationship | SAME | AS PA | GE 51 | | ISFE | M1 (T | YPE 4 |)PS | |
| | Not at all | Less than 1 per month | 1 or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | 1 per day | 2 or 3 per day | 4 or more per day |
| 5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse? | □. | | | | 4 | | □ ₆ | | 8 |
| | Not at all | Slightly | Moderately | Highly | Extreniely | SFEN | 13 (TY | PE 4)F | PS |
| 5.2 During this period, how interested have you been in sex? | | | | | 4 | | | | |
| 5.3 During this period, how satisfied have you been with your personal relationship with your sexual partner? | | | | | □₄ | SFEN | 14 (TY | PE 4)F | PS |
| | Could not be worse | Very poor | Poor | Somewhat inadequate | | Above average | Good | Very good | Could not be better |
| 5.4 In general, what would represent the best description of the quality of your sexual functioning? | | | | | | | | | |

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DATEHDR (TYPE 4)

P

| AGEID = 251 | Center Number: Particip | pant Number: | Participant's Initials: | first middle | |
|---------------------|-------------------------|--------------------|-------------------------|--------------|--|
| Duta completed: / / | OR Not done Smooth | - (delist beleve) | | | |

Derogatis Interview for Sexual Function (DISF-SR) (M) Male Version

Instruction: Below you will find a brief set of questions about your sexual activities. The questions are divided into different sections that ask about different aspects of your sexual experiences. One section asks about sexual fantasies or daydreams, while another inquires about the kinds of sexual experiences that you have. You are also asked about the nature of your sexual arousal and the quality of your orgasm. There are also a few other questions about different areas of your sexual relationship.

On some questions you are asked to respond in terms of a frequency scale, that is, "how often" do you perform the sexual activities asked about in that section. Some frequency scales go from "O = not at all" to "8 = four or more times a day." Other frequency scales range from "0 = never" to "4 = always." In the case of other questions, you will be asked to respond in terms of a satisfaction scale. This type of scale tells how much you enjoyed, or were satisfied by the sexual activity being asked about. Some satisfaction scales range from "0 = could not be worse" to "8 = could not be better." Other satisfaction scales go from "0 = not at all satisfied," to "4 = extremely satisfied."

In every section of the inventory the scales required for that section are printed just above the questions so it will be easy to follow. Although it is brief, take your time with the inventory. For each item, please check the scale number that best describes your personal experience.

If you have any questions, please ask the person who gave you the inventory for help.

DISMALE1 (TYPE 4)PS

| Section 1—Sexual Cognition/Fantasy | SAME A | AS PAG | SE 52 | | | | | | |
|--|---------------|--------------------------------|------------------------|---------------|-----------------------|-----------------------|--------------|----------------------|----------------------------|
| During the past 30 days or since the last time you filled out this inventory, how often have you had thoughts, dreams, or fantasies about: | Not at all | Less than 1 per month | 1 or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | 1 per day | 2 or 3 per day | 4 or more per day |
| 1.1 A sexually attractive person | □. | | | | □₄ | | | | □8 |
| 1.2 Erotic parts of a woman's body (e.g., face, genitals, legs) | □。 | | | \square_3 | □4 | \square_5 | □₀ | | □8 |
| 1.3 Erotic or romantic situations | □. | | | \square_3 | | \square_5 | □₀ | | □8 |
| 1.4 Caressing, touching, undressing, or foreplay | □, | | | \square_3 | □4 | \square_5 | Пб | \square_7 | □8 |
| 1.5 Sexual intercourse, oral sex, touching to orgasm | □. | | | Пз | | | | | □8 |
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| Not Done Codelist: 1 Participant refused 2 Clinician une | able to ob | otain 3 | Insufficier | nt time | 4 Instrum | nent failur | e 5 N | ot require | d |

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Participant's Initials:



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| | Center Num | ber: | Par | ticipant Nu | mber: | | Port | ticipant's l | nitials: | st middle last |
|--|------------------------|---------------|--------------------------------|------------------------|---------------|-----------------------|-----------------------|--------------|----------------------|----------------------------|
| Derogatis Interview for | Sexual F | unctio | n (DISF | -SR) (M) | Male Ve | rsion (co | ntinued) | | | |
| Section 2—Sexual Arousal | SAME AS P | AGE 53 | 3 | | DI | SMAL | .E1 (T` | YPE 4 | l)PS | |
| During the past 30 days or since the you filled out this inventory, how o you have the following experience | ften did | Not at all | Less than 1 per month | 1 or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | 1 per day | 2 or 3 per day | 4 or more per day |
| 2.1 A full erection upon awake | ning | □₀ | | | | 4 | | □₀ | | |
| 2.2 A full erection during a sex fantasy or daydream | ual | □, | | | | □4 | | □, | | □8 |
| 2.3 A full erection while looking sexually arousing person, repicture | | □. | | | | □ ₄ | | □₀ | | □8 |
| 2.4 A full erection during mastu | urbation | □. | | | | □ ₄ | | □, | | □8 |
| 2.5 A full erection throughout to of a normal sexual responsions that is from undressing and through intercourse and organization. | e cycle, I foreplay | | | | | _4 | | | | |

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Participant's Initials: first middle last

Durham NC 27705



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| Center Nu | mber: | Pa | rticipant Nu | ımber: | | Participant's Initials: first middle last | | | | |
|---|---------------|--------------------------------|------------------------|---------------|-----------------------|---|----------------|----------------------|----------------------------|--|
| Derogatis Interview for Sexual F | unctio | n (DISI | F-SR) (M) | Male Ve | rsion (co | ntinued) | | | | |
| Section 3—Sexual Behavior/Experiences | SAME | AS P | AGE 54 | D | ISMA | LE1 (| TYPE | 4)PS | | |
| During the past 30 days or since the last time you filled out the inventory, how often did you engage in the following sexual activities? | Not at all | Less than 1 per month | 1 or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | 1 per day | 2 or 3 per day | 4 or more per day | |
| 3.1 Reading or viewing romantic or erotic books or stories | | | | \square_3 | _4 | | 6 | | □ ₈ | |
| 3.2 Masturbation | □₀ | | | Пз | □4 | | □6 | | □8 | |
| 3.3 Casual kissing and petting | | | | Пз | _4 | | □ ₆ | | <u>*</u> | |
| 3.4 Sexual foreplay | | | | \square_3 | _4 | | □ ₆ | | □* | |
| 3.5 Sexual intercourse, oral sex, etc. | | | | 3 | | 5 | □ ₆ | | □, | |
| Section 4—Orgasm | | | | | DIS | MALE | =2 (T) | 'PE 4) | PS | |
| During the past 30 days or since the last time you filled out this inventory, how <u>satisfied</u> have you been with the following? | Not at all | Slightly | Moderately | Highly | Extremely | | | | | |
| 4.1 Your ability to have an orgasm | | | | 3 | | | | | | |
| 4.2 The intensity of your orgasm | | | | Пз | _4 | | | | | |
| 4.3 The length or duration of your orgasm | | | | | _4 | | | | | |
| 4.4 The amount of seminal liquid that you ejaculate | | | | | _4 | | | | | |
| 4.5 Your sense of control (timing) of your orgasm | | | | 3 | | | | | | |
| 4.6 Feeling a sense of relaxation and well-being after orgasm | | | | | 4 | | | | | |
| Copyright © 1987 by Leonard R. Derogatis, PhD. | | | | | | | | | | |

Durham NC 27705



PAGEID = 254

| Center | Number: | | Participant | Number: | | r | articipant | s Initials: | irst middle last | | | | |
|--|--------------------------|--------------------------------|------------------------|------------------------|-----------------------|-----------------------|-------------------|----------------------|----------------------------|--|--|--|--|
| Derogatis Interview for Sexua | l Func | tion (| DISF-SR) (| M) Male \ | ersion (| ontinue | 4) | | | | | | |
| Section 5—Drive and Relationship | SA | ME AS | PAGE : | 55 | DI | SMAL | .E1 (T | YPE 4 |)PS | | | | |
| | Not at all | Less than 1 per month | 1 or 2 per month | 1 per week | 2 or 3 per week | 4 to 6 per week | 1 per day | 2 or 3 per day | 4 or more per day | | | | |
| 5.1 With the partner of your choice, what would be your ideal frequency of sexual intercourse? | □₀ | | | □ ₃ | □₄ | | □₀ | | □8 | | | | |
| | Not at all | Slightly | Moderately | Highly | Extremely | , | | | | | | | |
| | | | | | DI | SMAL | SMALE2 (TYPE 4)PS | | | | | | |
| 5.2 During this period, how interested have you been in sex? | □₀ | | | Пз | □4 | | | | | | | | |
| 5.3 During this period, how satisfied | | | | | | | | | | | | | |
| have you been with your personal relationship with your | □₀ | □₁ | | □₃ | □₄ | | | | | | | | |
| sexual partner? | | | | | D | ISMA | LE3 (| ΓΥΡΕ ⁴ | 4)PS | | | | |
| | Could not be worse | Very poor | Poor | Somewhat inadequate | Adequate | Above average | Good | Very good | Could not be better | | | | |
| 5.4 In general, what would represent the best description of the quality of your sexual functioning? | □₀ | | | Пз | | | | | | | | | |

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CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012



Month 24 Submission

| | | | Ш, | |
|---|--|--|----|--|
| - | | | | |

| OFID OFF | | | | | Visit |
|---|----------------------|--------------------------|------------------------|-----------------|-----------------|
| GEID = 255 Center Number: Porticipon SAME AS PAGE 3 | t Number: | | Participa | ınt's Initials: | first middle la |
| Date completed: $_{day}$ / $_{month}$ / $_{year}$ OR Not done \rightarrow Specify 1 | eason (use a | codelist belo | Ä ^{):} EHD | R (TYF | PE 4) |
| Food Cravings Questionnaire—State (FCQ—S) | | | | | |
| Below is a list of comments made by people about their eating habits. Please now much you agree with the comment right now, at this very moment. while others refer to one or more specific foods. Please respond to each item | Notice that | some ques y as possib | tions refer | to foods in | general |
| SAME AS PAGE 58 | Strongly Disagree | Disagree | | | Strong Agree |
| I have an intense desire to eat [one or more specific foods]. | | | 3 | 4 | |
| 2 I'm craving [one or more specific foods]. | | | \square_3 | | |
| 3 I have an urge for [one or more specific foods] | | | 3 | | |
| Eating [one or more specific foods] would make things seem just perfect. | | | | | |
| If I were to eat what I am craving, I am sure my mood would improve. | | | | | |
| Eating [one or more specific foods] would feel wonderful. | | | | | |
| If I ate something, I wouldn't feel so sluggish and lethargic. | | | | | |
| Satisfying my craving would make me feel less grouchy and irritable. | | | | | |
| I would feel more alert if I could satisfy my craving. | | | Пз | | |
| 10 If I had [one or more specific foods], I could not stop eating it. | | | | | |
| 11 My desire to eat [one or more specific foods] seems overpowering. | | | | | |
| 12 I know I'm going to keep on thinking about [one or more specific foods] until I actually have it. | | | | | |
| 13 I am hungry. | | | | 4 | □₅ |
| 14 If I ate right now, my stomach wouldn't feel as empty. | | | | | |
| 15 I feel weak because of not eating. | Ι Π, | | | Π, | |

CALERIE PHASEE2 ANNOTATION V8.0

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain

Participant's Initials: first middle last

· Durham NC 27705

4 Instrument failure

5 Not required

Send to DCR

3 Insufficient time



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| Cent | er Number: | Participant Number: | | Participant's | Initials: |
|--|-----------------------|---------------------------|----------------------|-------------------|----------------------------|
| Date completed:/ _{month} _/ _{year} _ | OR Not done | Specify reason (a | se codelist belov | X): | TVPE 1) |
| Food Craving Inventory (FCI-II) | | 7.02 | יט | (I E I I DIC | T |
| For each of the foods listed below, please chec | | ox. | C | RAVE (T | YPE 4)PS |
| Note: A craving is defined as an intense desire | to consume a parti | | type that is dif | ficult to resist. | Almana / Alma at |
| Over the past month, how often have you experienced a craving for | Never | Rarely (once or twice) | Sometimes | Often | Always/Almost Every Day |
| 1 Cake SAME AS PAGE 5 | 59 🔲 1 | | Пз | | \square_5 |
| 2 Pizza | | | З | | |
| 3 Fried chicken | | | □₃ | | \square_5 |
| 4 Gravy | | | □₃ | | |
| 5 Sandwich bread | | | □₃ | | |
| 6 Sausage | | | □₃ | | |
| 7 French fries | | | □₃ | | |
| 8 Cinnamon rolls | | | □₃ | | \square_5 |
| 9 Rice | | | ₃ | | |
| 10 Hot dog | | | ₃ | | |
| 11 Hamburger | | | \square_3 | | |
| 12 Biscuits | | | ₃ | | |
| 13 Ice cream | | | ₃ | | |
| 14 Pasta | | | З | | |
| 15 Fried fish | | | З | | |
| 16 Cookies | | | З | | |
| 17 Chocolate | | | ₃ | | |
| 18 Pancakes or waffles | | | З | | |
| 19 Corn bread | | |]3 | | 5 |
| 20 Chips | | | \square_3 | | |
| 21 Rolls | | | З | | |
| 22 Cereal | | | ₃ | | |
| 23 Donuts | | | | | |
| 24 Candy | | | \square_3 | | |
| 25 Brownies | | | З | | |
| 26 Bacon | | | Пз | | |
| 27 Steak | | | | | |
| 28 Baked potato | | | | | |
| Not Done Codelist: 1 Participant refused 2 Cli | nician unable to obta | in 3 Insufficient ti | me 4 Instrume | nt failure 5 N | Not required |
| CALERIE PHASEI | E2 ANNOTATIO | N V8.0 24FEB | 2012 | Participant's l | nitials: |

Send to DCRI Forms Management · 2400 Pratt St. · Room 0311 Terrace Level · Durham NC 27705



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| | Cente | er Number: | Participant Number: | | Participant's I | nitials: |
|-------|---|--|--|-----------------------------|----------------------|--------------|
| | completed:/ _{month} / _{year} | OR Not done → SAME AS | Specify reason (use co | odelist below): | Γ EHD R (| TYPE 4) |
| Eati | ng Inventory | | | | | |
| 1 | When I smell a sizzling steak or difficult to keep from eating, eve | r see a juicy pie en if I have just | ce of meat, I find finished a meal. | it very TF | EQA (T) | PE 4)PS |
| 2 | I usually eat too much at social | occasions, like | | s. <mark>ME AS PA</mark> | | o False |
| 3 | I am usually so hungry that I ed | ıt more than th | | WE NOT A | | o False |
| 4 | When I have eaten my quota of not eating anymore. | f calories, I am | usually good abo | out | ☐ ₁ True | □₀ False |
| 5 | Dieting is so hard for me becau | se I just get too | hungry. | | ☐₁ True | □₀ False |
| 6 | I deliberately take small helping | gs as a means o | of controlling my v | weight. | , True | o False |
| 7 | Sometimes things just taste so g I am no longer hungry. | ood that I keep | on eating even v | vhen | □₁ True | □₀ False |
| 8 | Since I am often hungry, I some expert would tell me that I have something more to eat. | | | g, an | □₁ True | o False |
| 9 | When I feel anxious, I find myse | elf eating. | | | ☐₁ True | o False |
| 10 | Life is too short to worry about | dieting. | | | | o False |
| 11 | Since my weight goes up and d more than once. | own, I have go | ne on reducing di | ets | □₁ True | □₀ False |
| 12 | I often feel so hungry that I just | have to eat so | mething. | | ☐₁ True | o False |
| 13 | When I am with someone who | is overeating, l | usually overeat to | 00. | ☐₁ True | □₀ False |
| 14 | I have a pretty good idea of the | number of cal | ories in common | food. | , True | □₀ False |
| 15 | Sometimes when I start eating, | l just can't seer | n to stop. | | ☐, True | o False |
| 16 | It is not difficult for me to leave | something on r | my plate. | | ☐₁ True | □₀ False |
| 17 | At certain times of the day, I ge to eating then. | t hungry becau | se I have gotten u | used | □₁ True | □₀ False |
| 18 | While on a diet, if I eat food the for a period of time to make up | | d, I consciously ec | ıt less | ☐₁ True | □₀ False |
| Not D | one Codelist: 1 Participant refused 2 Clir | nician unable to obta | in 3 Insufficient time | 4 Instrument | failure 5 N | lot required |
| | | | | | | |

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last



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| | Center Number: Participant Number: | Participant's In | first middle last |
|------|---|---------------------|-------------------|
| Eati | ing Inventory (continued) | | |
| 19 | Being with someone who is eating often makes me hungry to eat also. | □₁ True | o False |
| 20 | SAME AS PAGE 61 When I feel blue, I often overeat. | TFEQA (TY | PE 4)PS Gralse |
| 21 | I enjoy eating too much to spoil it by counting calories or watching my weight. | ☐₁ True | □₀ False |
| 22 | When I see a real delicacy, I often get so hungry that I have to eat right away. | ☐₁ True | □₀ False |
| 23 | I often stop eating when I am not really full as a conscious means of limiting the amount I eat. | ☐₁ True | □₀ False |
| 24 | I get so hungry that my stomach often seems like a bottomless pit. | ☐ ₁ True | □₀ False |
| 25 | My weight has hardly changed at all in the last ten years. | ☐ ₁ True | □₀ False |
| 26 | I am always hungry so it is hard for me to stop eating before I finish the food on my plate. | ☐₁ True | □₀ False |
| 27 | When I feel lonely, I console myself by eating. | ☐₁ True | □₀ False |
| 28 | I consciously hold back at meals in order not to gain weight. | ☐₁ True | □₀ False |
| 29 | I sometimes get very hungry late in the evening or at night. | ☐₁ True | □₀ False |
| 30 | I eat anything I want, any time I want. | ☐₁ True | □₀ False |
| 31 | Without even thinking about it, I take a long time to eat. | ☐ ₁ True | □₀ False |
| 32 | I count calories as a conscious means of controlling my weight. | ☐₁ True | o False |
| 33 | I do not eat some foods because they make me fat. | ☐₁ True | □₀ False |
| 34 | I am always hungry enough to eat at any time. | ☐₁ True | o False |
| 35 | I pay a great deal of attention to changes in my figure. | ☐, True | □₀ False |
| 36 | While on a diet, if I eat a food that is not allowed, I often splurge and eat other high calorie foods. | □₁ True | □₀ False |

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: first middle last



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| | Center Number: | Participant Number: Participant's Initials: first middle last |
|------|---|---|
| Eat | ing Inventory (continued) | |
| Plea | se check one answer that is most appropriate to you | |
| 37 | How often are you dieting in a conscious AS effort to control your weight? | SPARF62 _2 Sometimes _3 Usually _4 Always |
| 38 | Would a weight fluctuation of 5 pounds affect the way you live your life? | \square_1 Rarely \square_2 Sometimes \square_3 Usually \square_4 Always |
| 39 | How often do you feel hungry? | \square_1 Rarely \square_2 Sometimes \square_3 Usually \square_4 Always |
| 40 | Do your feelings of guilt about overeating help you to control your food intake? | ☐₁ Rarely ☐₂ Sometimes ☐₃ Usually ☐₄ Always |
| 41 | How difficult would it be for you to stop eating halfway through dinner and not eat for the next four hours? | ☐₁ Easy ☐₂ Slightly difficult ☐₃ Moderately difficult ☐₄ Very difficult |
| 42 | How conscious are you of what you are eating? | ☐₁ Not at all ☐₂ Slightly ☐₃ Moderately ☐₄ Extremely |
| 43 | How frequently do you avoid "stocking up" on tempting foods? | \square_1 Almost never \square_2 Seldom \square_3 Usually \square_4 Almost always |
| 44 | How likely are you to shop for low calorie foods? | ☐, Unlikely ☐₂ Slightly likely ☐₃ Moderately likely ☐₄ Very likely |
| 45 | Do you eat sensibly in front of others and splurge alone? | □₁ Never □₂ Rarely □₃ Often □₄ Always |
| 46 | How likely are you to consciously eat slowly in order to cut down on how much you eat? | ☐, Unlikely ☐₂ Slightly likely ☐₃ Moderately likely ☐₄ Very likely |
| 47 | How frequently do you skip dessert because you are no longer hungry? | \square_1 Almost never \square_2 Seldom \square_3 At least once a week \square_4 Almost every day |
| 48 | How likely are you to consciously eat less than you want? | ☐₁ Unlikely ☐₂ Slightly likely ☐₃ Moderately likely ☐₄ Very likely |
| 49 | Do you go on eating binges though you are not hungry? | Never 2 Rarely 3 Sometimes 4 At least once a week |
| 50 | To what extent does this statement describe your eating behavior? "I start dieting in the morning, but because of any number of things that happen during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow." | ☐₁ Not like me ☐₂ Little like me ☐₃ Pretty good description of me ☐₄ Describes me perfectly |
| 51 | On a scale of 0 to 5, where 0 means no restraint in eating (eating whatever you want, whenever you want it) and 5 means total restraint (constantly limiting food intake and never "giving in"), what number would you give yourself? | □₀ Eat whatever you want, whenever you want it □₁ Usually eat whatever you want, whenever you want it □₂ Often eat whatever you want, whenever you want it □₃ Often limit food intake, but often "give in" □₄ Usually limit food intake, rarely "give in" □₅ Constantly limiting food intake, never "giving in" |

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Participant's Initials: first middle last

rham NC 27705



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| | | | | | | | | | | W 14 | 911 I |
|---|--|--|--------------------------------|--|--|-----------------------------|--|--------------------|----------------------------------|---|--|
| =ID = 260 | Center Number: _ | | Particip | oant Nur | nber: _ | | | Particip | ant's Init | ials: | middle last |
| te completed:/ _{month} / | OR Not | done – | Specif | y reaso | on (use) | codelist | below): DA | TEHE | DR (T | YPE | 4) |
| is form describes some typical eating si wn. The following are a number of situ ting situations which you find the hard Read each situation listed below and the difficult situations. In other words, 9 (very confident), choose ONE number | tuations. Everyonations relating to est to manage. decide how confibrated that you contibrated that you contibrated that reflects how | e has sit eating p dent (or are in th v confid SAME | certain e eating ent you | s and a s) you o g situat s feel no PAGE | ttitudes are that ion righ ow abo | you w nt now. ut bein | orm wil ill be al On a s g able | ble to recale from | esist ear om 0 (no essfull | ting in e ot confic y resis 4)PS | he each dent) • the |
| m confident that: | | | | | | eat 4 | уо 5 | | | | |
| I can resist eating when I am (nervous). | anxious | | | | | | | | | □ ₈ | |
| I can control my eating on the | weekends. | □。 | | | \square_3 | \square_4 | \square_5 | □ ₆ | □ ₇ | □, | □ ₉ |
| I can resist eating even when say "no" to others. | I have to | □₀ | | | З | | | 6 | | □, | |
| I can resist eating when I feel run down. | physically | \Box_{\circ} | | | \square_3 | \square_4 | | | \square_7 | | |
| I can resist eating when I am | watching TV. | | | | Пз | _4 | | 6 | | □ ₈ | |
| I can resist eating when I am (or down). | depressed | \Box_{\circ} | | | \square_3 | \square_4 | \square_5 | □ ₆ | □ ₇ | □8 | |
| I can resist eating when there different kinds of food availal | are many ble. | | | | З | | | 6 | | □. | |
| | | | | | Пз | | | □ ₆ | | | |
| | /eight Efficacy Lifestyle (is form describes some typical eating siwn. The following are a number of situ ting situations which you find the hards Read each situation listed below and the difficult situations. In other words, 19 (very confident), choose ONE number sire to eat. Check this number for each time confident that: I can resist eating when I am (nervous). I can control my eating on the law "no" to others. I can resist eating when I feel run down. I can resist eating when I am (or down). I can resist eating when I am (or down). | te completed: | te completed: | te completed: | te completed: | te completed: | te completed: | te completed: | te completed: | Center Number: Porticipant Number: Porticipant's Init te completed: | Center Number: Participant Number: Participant's Initials: te completed: |

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

2 Clinician unable to obtain

Participant's Initials: first middle last

5 Not required

4 Instrument failure

3 Insufficient time

headache.

I can resist eating even when I have a

Not Done Codelist: 1 Participant refused



PAGEID = 261

| Weight Efficacy Lifestyle Questionnaire (WEL) (continued) I am confident that: SAME AS PAGE 64 Not confident at all that you can resist the desire to eat you can resist the desire to eat well of the you can resist the desire to eat well (TYPE 4)PS 10 can resist eating when am reading. 1 can resist eating when am angry | | Center Number: | _ | Particip | ant Nun | nber: _ | | | Particip | ant's Init | ials: | middle last |
|--|---|----------------|----------------|-------------|-------------|-------------|---------------|-------------|------------------|------------------|----------------|--------------|
| Jam confident that: SAME AS PAGE 64 you can resist the desire to eat WELQ (TYPE 4)PS 9 10 I can resist eating when I am reading. 11 can resist eating when I am angry | Weight Efficacy Lifestyle (| Questionnaire |) (w | EL) (co | ntinued | l) | | | | | | |
| 10 can resist eating when am reading. 11 can resist eating when am angry | I am confident that: | GE 64 y | ou ca | n resis | t the de | sire to | | WEL | u can r .Q_(T | esist the YPE | desire 4)PS | to eat |
| 11 can resist eating when am angry | | | | | | | _ | | | | | |
| 12 can resist eating even when am at a party. | 10 I can resist eating when I am | reading. | \square_{0} | | | З | \square_4 | \square_5 | □ ₆ | | □8 | |
| a party. 13 can resist eating even when others are pressuring me to eat. 14 can resist eating when am in pain. | | angry | \Box_{\circ} | | | З | | | 6 | | □, | |
| pressuring me to eat. 0 | • | I am at | | | | \square_3 | \square_{4} | \square_5 | 6 | | □, | |
| 15 I can resist eating just before going to bed. 16 I can resist eating when I have experienced failure. 17 I can resist eating when high-calorie foods are available. 18 I can resist eating even when I think others will be upset if I don't eat. 19 I can resist eating when I feel uncomfortable. | | others are | \Box_{o} | | | З | 4 | | | | □, | |
| bed. 16 I can resist eating when I have experienced failure. 17 I can resist eating when high-calorie foods are available. 18 I can resist eating even when I think others will be upset if I don't eat. 19 I can resist eating when I feel uncomfortable. | 14 I can resist eating when I am | in pain. [| \Box_{\circ} | | | Пз | \square_{4} | \square_5 | □ ₆ | _ ₇ | □, | |
| experienced failure. 0 | ~ . | going to | \Box_{o} | | | Пз | _4 | | 6 | | □8 | |
| are available. 18 I can resist eating even when I think others will be upset if I don't eat. 19 I can resist eating when I feel uncomfortable. 10 I I I I I I I I I I I I I I I I I I I | 16 I can resist eating when I have experienced failure. | e [| \Box_{o} | | \square_2 | \square_3 | \square_{4} | \square_5 | 6 | | □, | ₉ |
| others will be upset if I don't eat. 19 I can resist eating when I feel uncomfortable. 10 I I I I I I I I I I I I I I I I I I I | | calorie foods | \Box_{o} | | | З | 4 | | 6 | | □, | |
| uncomfortable. | | | \Box_{\circ} | \square_1 | | \square_3 | \square_{4} | \square_5 | 6 | | □, | |
| 20 I can resist eating when I am happy. \[\bigcup_0 \bigcup_1 \bigcup_2 \bigcup_3 \bigcup_4 \bigcup_5 \bigcup_6 \bigcup_7 \bigcup_8 \bigcup_9 \] | | | | | | З | | | □6 | | | |
| | 20 I can resist eating when I am | happy. | | | | \square_3 | | | 6 | | □ ₈ | |

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Participant's Initials: first middle last



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| AGEID = 202 | Center Number: | Participant N | pant Number: Participant's Initials: | | | | middle last | | |
|--|--|------------------------|--------------------------------------|----------------|-------------|----------------|-------------|----------------|--------|
| Date completed:/ | SAME AS F OR Not done \rightarrow | PAGE 36 Specify red | ason | (use code | elist below | ATFHI | DR (T | YPE | 4) |
| Multiaxial Assess | ment of Eating Disorder | Sympto | om | S (MAE | | IALD | 5 (11 | |)1 0 |
| Instructions: Using the scale | e shown, please rate the following items o | on a scale fi | rom 1 | to 7. Ple | ase ansv | ver as tru | thfully o | as possil | ble. |
| | SAME AS PAGE 65 | N | ever | Very Rarely | Rarely | Some- times | Often | Very Often | Always |
| 1 Fasting is a good w | vay to lose weight. | | \Box_1 | | \square_3 | 4 | 5 | 6 | |
| 2 My sleep isn't as g | ood as it used to be. | | \Box_1 | | Пз | | | □₀ | |
| 3 I avoid eating for a | ıs long as I can. | | \Box_1 | | \square_3 | | | 6 | |
| 4 Certain foods are " | 'forbidden" for me to eat. | | \Box_{1} | | \square_3 | \square_{4} | \square_5 | | |
| 5 I can't keep certain f binge on them. | foods in my house because I will | | ₁ | | \square_3 | 4 | | 6 | |
| 6 I can easily make n | myself vomit. | | \Box_1 | | \square_3 | | 5 | 6 | |
| 7 I can feel that being | g fat is terrible. | | \Box_1 | | \square_3 | 4 | 5 | □ ₆ | |
| 8 I avoid greasy food | ds. | | \Box_1 | | Пз | | | 6 | |
| 9 It's okay to binge o | and purge once in a while. | | \Box_1 | | Пз | | 5 | 6 | |
| 10 I don't eat certain f | foods. | | \Box_1 | | \square_3 | \Box_4 | 5 | 6 | |
| 11 I think I am a good | l person. | | \Box_1 | | Пз | | 5 | 6 | |
| 12 My eating is norma | al. | | \Box_1 | | Пз | | | 6 | |
| 13 I can't seem to con- | centrate lately. | | \Box_1 | | Пз | | | 6 | |
| 14 I try to diet by fasti | ing. | | \Box_1 | | Пз | □₄ | \square_5 | □₀ | |
| 15 I vomit to control m | ny weight. | | \Box_1 | | \square_3 | | 5 | 6 | |
| 16 Lately nothing seen | ms enjoyable anymore. | | \square_1 | | \square_3 | | \square_5 | 6 | |
| 17 Laxatives help keep | p you slim. | | \Box_1 | | | | 5 | G | |
| 18 I don't eat red med | ıt. | | \Box_1 | | | □₄ | 5 | | |
| 19 I eat so rapidly I co | an't even taste my food. | | \Box_1 | | З | | 5 | 6 | |
| Not Done Codelist: 1 Partic | ipant refused 2 Clinician unable to obtain | n 3 Insuff | icient | time 4 | Instrume | nt failure | 5 No | t require | d |

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Durham NC 27705



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MAEDS (TYPE 4)PS

| Center Number: Por | ticipant N | umber: _ | | Pa | rticipant's | Initials: _ | irst middle last |
|--|------------|----------------|--------|----------------|-------------|---------------|------------------|
| Multiaxial Assessment of Eating Disorder Sy | mpto | ms (| MAEDS) | (continue | d) | | |
| SAME AS PAGE 66 | Never | Very Rarely | Rarely | Some- times | Often | Very Often | Always |
| 20 I do everything I can to avoid being overweight. | | | 3 | | | □, | |
| 21 When I feel bloated, I must do something to rid myself of that feeling. | | | □₃ | | | □6 | |
| 22 I overeat too frequently. | | | 3 | | | □, | |
| 23 It's okay to be overweight. | □₁ | | 3 | | | 6 | |
| 24 Recently I have felt that I am a worthless person. | | | Пз | | | □, | |
| 25 I would be very upset if I gained 2 pounds. | | | 3 | | | 6 | |
| 26 I crave sweets and carbohydrates. | | | | | | 6 | |
| 27 I lose control when I eat. | | | Пз | | | _6 | |
| 28 Being fat would be terrible. | | | 3 | | | □6 | |
| 29 I have thought seriously about suicide lately. | □₁ | | Пз | | | 6 | |
| 30 I don't have any energy anymore. | | | З | | | 6 | |
| 31 I eat small portions to control my weight. | | | Пз | | | 6 | |
| 32 l eat 3 meals a day. | | | З | 4 | | 6 | |
| 33 Lately I have been easily irritated. | □₁ | | Пз | | | □6 | |
| 34 Some foods should be totally avoided. | | | 3 | 4 | | 6 | |
| 35 I use laxatives to control my weight. | | | Пз | | | _6 | |
| 36 I am terrified by the thought of being overweight. | | | Пз | | | 6 | |
| 37 Purging is a good way to lose weight. | | | Пз | | | □, | |
| 38 I avoid fatty foods. | | | | | | □, | |

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

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Month 24 Submission

MAEDS (TYPE 4)PS

PAGEID = 264

Center Number: ____ Participant Number: ____ Participant's Initials:

| Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (continued) | | | | | | | | |
|---|-------|----------------|-------------|----------------|---------------|----------------|--------|--|
| SAME AS PAGE 67 | Never | Very Rarely | Rarely | Some- times | Often | Very Often | Always | |
| 39 Recently I have felt pretty blue. | | | | | 5 | G | | |
| 40 I am obsessed with becoming overweight. | | | _3 | □₄ | \square_{5} | | | |
| 41 I don't eat fried foods. | | | 3 | 4 | 5 | | | |
| 42 I skip meals. | | | 3 | □₄ | \square_5 | | | |
| 43 Fat people are unhappy. | | | \square_3 | 4 | 5 | 6 | | |
| 44 People are too concerned with the way I eat. | | | _3 | □₄ | 5 | 6 | | |
| 45 I feel good when I skip meals. | | | \square_3 | 4 | 5 | 6 | | |
| 46 I avoid foods with sugar. | | | \square_3 | □₄ | 5 | □, | | |
| 47 I hate it when I feel fat. | | | 3 | □4 | 5 | 6 | | |
| 48 I am too fat. | | | \square_3 | □₄ | \square_5 | □, | | |
| 49 I eat until I am completely stuffed. | | | 3 | 4 | 5 | □6 | | |
| 50 I hate to eat. | | | Пз | □₄ | \square_5 | □, | | |
| 51 I feel guilty about a lot of things these days. | | | \square_3 | □₄ | 5 | □ ₆ | | |
| 52 I'm very careful of what I eat. | | | □₃ | □₄ | \square_{5} | □, | | |
| 53 I can "hold off" and not eat even if I am hungry. | | | 3 | 4 | 5 | 6 | | |
| 54 I eat even when I am not hungry. | | | Пз | □₄ | \square_{5} | | | |
| 55 Fat people are disgusting. | | | 3 | □₄ | 5 | | | |
| 56 I wouldn't mind gaining a few pounds. | | | Пз | □₄ | | | | |

CALERIE PHASEE2 ANNOTATION V8.0
24FEB2012

2010 DCRI — Confidential

Participant's Initials: first middle last

ham NC 27705

CRF, page 264

| | | Phase | 2 |
|-----|--|-------|---|
| cal | | | |

| GE | EID = 265 | | | | , . | | J., , |
|----|---|--------------|----------|----------------|--------------|---------------|---------------|
| Da | te completed:// | | | | ticipant's l | fire | t middle last |
| В | ody Shape Questionnaire (BSQ) | | | DATE | HUK (| ITPE | 4) |
| We | would like to know how you have been feeling about your appearance o ase read each question and check the box for the appropriate choice. Plea | | | | | (TYPI | ∃ 4)P |
| Ov | same as Page 68 | Never | Rarely | Some- times | Often | Very Often | Always |
| 1 | Has feeling bored made you brood about your shape? | | | 3 | 4 | 5 | |
| 2 | Have you been so worried about your shape that you have been feeling that you ought to diet? | | | З | □₄ | 5 | |
| 3 | Have you thought that your thighs, hips, or bottom are too large for the rest of you? | | | | _4 | 5 | |
| 4 | Have you been afraid that you might become fat (or fatter)? | | | Пз | | | |
| 5 | Have you worried about your flesh not being firm enough? | | | | _4 | 5 | |
| 6 | Has feeling full (e.g., after eating a large meal) made you feel fat? | | | | | | |
| 7 | Have you felt so bad about your shape that you have cried? | | | | 4 | 5 | |
| 8 | Have you avoided running because your flesh might wobble? | | | \square_3 | | | |
| 9 | Has being with thin women/men made you feel self-conscious about your shape? | | | | _4 | 5 | |
| 10 | Have you worried about your thighs spreading out when sitting down? | | | Пз | □4 | | |
| 11 | Has eating even a small amount of food made you feel fat? | | | | _4 | 5 | |
| 12 | Have you noticed the shape of other women/men and felt that your own shape compared unfavorably? | | | Пз | \Box_4 | | |
| 13 | Has thinking about your shape interfered with your ability to concentrate (e.g., while watching TV, reading, listening to conversations)? | | | | _4 | | |
| 14 | Has being naked, such as when taking a bath, made you feel fat? | | | Пз | □4 | | |
| 15 | Have you avoided wearing clothes which make you particularly aware of the shape of your body? | | | | _4 | 5 | |
| 16 | Have you imagined cutting off fleshy areas of your body? | | | Пз | □₄ | | |
| No | ot Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insuf | ficient time | 4 Instri | ument failu | ire 5 N | lot require | d |

CALERIE PHASEE2 ANNOTATION V8.0 24FEB2012

Participant's Initials: First middle last

Durham NC 27705

Send to DCR



PAGEID = 266

BSQ (TYPE 4)PS

| Celler Holliber. | donnoer | | | napan s | filliois. | irst middle last |
|--|---------|--------|----------------|---------|---------------|------------------|
| Body Shape Questionnaire (BSQ) (continued) | | | | | | |
| Over the Past Four Weeks SAME AS PAGE 69 | Never | Rarely | Some- times | Often | Very Often | Always |
| 17 Has eating sweets, cakes or other high calorie food made you feel fat? | | | □₃ | | □₅ | □6 |
| 18 Have you not gone out on social occasions (e.g., parties) because you have felt bad about your shape? | | | З | □₄ | | □6 |
| 19 Have you felt excessively large and rounded? | | | Пз | _4 | 5 | 6 |
| 20 Have you felt ashamed of your body? | | | Пз | □₄ | | □₀ |
| 21 Has worry about your shape made you diet? | | | □₃ | 4 | | |
| 22 Have you felt happiest about your shape when your stomach has been empty? | | | Пз | _4 | | 6 |
| 23 Have you thought that you are the shape you are because you lack self-control? | | | З | _4 | 5 | 6 |
| 24 Have you worried about other people seeing rolls of flesh around your waist or stomach? | | | □₃ | □₄ | | □6 |
| 25 Have you felt that it is not fair that other women/men are thinner than you? | | | Пз | | | □6 |
| 26 Have you vomited in order to feel thinner? | □₁ | | Пз | □₄ | | □6 |
| 27 When in company, have you worried about taking up too much room (e.g., sitting on a sofa or bus seat)? | | | Пз | 4 | | 6 |
| 28 Have you worried about your flesh being dimply? | | | Пз | □₄ | | □6 |
| 29 Has seeing your reflection (e.g., in a mirror or shop window) made you feel bad about your shape? | | | | | | |
| 30 Have you pinched areas of your body to see how much fat is there? | | | | 4 | | 6 |
| 31 Have you avoided situations where people could see your body (e.g., communal changing rooms or swimming pools)? | | | | 4 | | □ ₆ |
| 32 Have you taken laxatives in order to feel thinner? | | | | | | □6 |
| 33 Have you been particularly self-conscious about your shape when in the company of other people? | | | Пз | | | |
| 34 Has worry about your shape made you feel you ought to exercise? | | | | | | |

Participant's Initials: first middle last



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| | Center Number | ": Participant Num | iber: Pari | first middle last | | | | | |
|--|----------------------------|-----------------------------|----------------------------|-------------------|--|--|--|--|--|
| Handgrip Strength | | | | | | | | | |
| Date and time of assessment: $\frac{1}{2} - \frac{1}{2} - \frac{1}{2} = \frac{1}{2} - \frac{1}{2} = \frac{1}{$ | | | | | | | | | |
| Dynometer handle position: | | | | | | | | | |
| 2 Dominant hand (check only one): 1 Left 2 Right 3 Ambidextrous 3 Handgrip strength: SAME AS PAGE 77 HANDGRIP (TYPE 4)PS | | | | | | | | | |
| Handgrip Strength | Zero Meter Check | Right Hand | Zero Meter Check Left Hand | | | | | | |
| Test 1—peak force | □₀ | kg | □₀ | kg | | | | | |
| Test 2—peak force | □₀ | kg | □₀ | kg | | | | | |
| Test 3—peak force | | kg | | kg | | | | | |
| | | | | | | | | | |
| Not Done Codelist: 1 Participar | nt refused 2 Clinician una | uble to obtain 3 Insufficie | nt time 4 Instrument failu | re 5 Not required | | | | | |



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| | | | Center Number: | Participant N | Number: _ | | Particip | pant's Initials: first middle last | |
|----|--|--------------|--|---------------|--|--------------------|----------|--|--|
| ls | ometric/Isokine | tic Knee | Extension and | Flexion | i | | | | |
| | ate and time of assessment | | | | - | DATEU | | first middle last | |
| 01 | R Not done → Specify rea | son (use cod | elist below): <u>SA</u> IVIL AS | FAGL 4 | | DATEH | JK (1 | TPE 4) | |
| 1 | 10 10 10 10 10 10 10 10 10 10 10 10 10 1 | | | | | | | | |
| 2 | Recent injury or pain—lef | t knee? | \Box_0 No \Box_1 Yes | PAGE 78 | IS | OMETR | C (IY | PE 4)PS | |
| 3 | Specify machine used (PE | BRC only): [| □ ₀ Cybex □ ₁ Biolex | MACHIN | NE <tu< th=""><th>SED></th><th></th><th></th></tu<> | SED> | | | |
| | All values corrected | for gravit | y effect torque | Right | Leg | Left L | eg | If Not Done, Specify Reason (Use codelist below) | |
| 3 | 60°/sec knee extension | | peak torque | | N.m | E 33 33 33 3 | _N.m | | |
| | | | total work | | N.m | | _N.m | | |
| | | | average power | | watts | | _ watts | | |
| 4 | $60^{\circ}/\text{sec}$ knee flexion | | peak torque | | N.m | | _N.m | | |
| | | | total work | | N.m | | _N.m | | |
| | | | average power | | watts | | _watts | | |
| 5 | 180°/sec knee extension | | peak torque | | N.m | - 2 2 - | _N.m | | |
| | | | total work | | N.m | | _N.m | | |
| | | | average power | | watts | - | _watts | | |
| | | | work fatigue index | | . % | | _ % | | |
| 6 | 180°/sec knee flexion | | peak torque | | N.m | | _N.m | | |
| | | | total work | | N.m | | _ N.m | | |
| | | | average power | - | watts | | _watts | | |
| | | | work fatigue index | | . % | | _ % | | |
| 7 | Isometric knee extension: | trial 1 | peak torque | | N.m | | _N.m | | |
| | | trial 2 | peak torque | | N.m | | _N.m | - | |
| | | trial 3 | peak torque | | N.m | | _ N.m | | |
| 8 | Isometric knee flexion: | trial 1 | peak torque | | N.m | | _N.m | | |
| | | trial 2 | peak torque | | N.m | | _N.m | | |
| | | trial 3 | peak torque | | N.m | | _ N.m | | |
| | | | | | | | | | |

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



PAGEID = 269

| | Center Nun | nber: Participant N | lumber: Participant's Initials: | first middle las |
|-----------------------------|--------------------------------|------------------------------|--|------------------|
| Clinic Weight | | | | |
| | day / | | Staff initials: $\frac{1}{fest \ middle}$ | |
| Clinic weight (if the two n | neasurements are more than 0.1 | l kg apart, measure weight a | third time): | |
| Weight 1: | kg | SAME AS PA | AGE 4 WEIGHT (TYPE 4) | |
| Weight 2: | kg | | | |
| Weight 3: | kg | | | |
| Weight of gown: | kg | | | |
| Not Done Codelist: 1 Po | articipant refused 2 Clinician | unable to obtain 3 Insuffic | cient time 4 Instrument failure 5 Not requ | ired |

calerie Phase 2

PAGEID = 270

Month 24 Submission Visit 2

| Center Number: | Participant Number: | | Participant's Initials: | | | _ |
|----------------|---------------------|---------------|-------------------------|----------|-------|----|
| | | PARHDR | (TYPE 4) | first mi | iddle | fa |

| Se | Seven-Day Physical Activity Recall (PAR) | | | | | | | | | | | | | | |
|------------------------------|---|-----------------------------|----------------|--|------------------|---------------------|------|-------------|--------------|------------------------|----------------|-----------------|--------------------|------|--------------|
| Tod | Today's date:/ | | | | | | | | | | | | | | |
| | 1 Were you employed in the last seven days? □ No → Skip to question 3 □ Yes Interviewer initials: Interviewer initials: | | | | | | | | | | | | | | |
| 2 | 2 If Yes: Which days (check all that apply)? | | | | | | | | | | | | | | |
| 3 | Which d | lays do you consider your w | | | | Tues | | | Fri _ | Sat | | | | | |
| Day | Day of | Date | Slee | p Time | Work | Time | Mor | ning (in mi | | Afternoon (in minutes) | | | Evening (in minute | | |
| # | Week | Date | In Bed | Up | Start | Stop | Mod. | Hard | Very Hard | Mod. | Hard | Very Hard | Mod. | Hard | Very Hard |
| 7 (yester- day) | | / | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | P <u>ARC</u> I | <u> HT (T</u>) | (PE 4) | PS | |
| 6 | | / | 00:00 to 23:59 | 00:00 to 23:59 | ::00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
| 5 | | / | 00:00 to 23:59 | 00:00 to 23:59 : : : : : : : : : : | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
| 4 | | day month year | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | SAI | ME AS I | PAGE 7 | 1 | | | | |
| 3 | | / | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:69 | 00:00 to 23:59 | | | | | | | | | |
| 2 | | / | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | : 00:00 to 23:59 | | | | | | | | | |
| ¶ (1 weel ago) | S. | / | 00:00 to 23:59 | 00:00 to 23:59 | | 00:00 to 23:59 | | | | | | | | | |

5 Not required Not Done Codelist: 1 Participant refused



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| | | Center Number: | Participant Number: | Participant's Initials: | first middle last |
|----|---|-----------------------------|-------------------------------|-------------------------|-------------------|
| S | even-Day Physical Activ | vity Recall (PAR) (co | ntinued) | | |
| 4 | Compared to your physical activity | over the past three month: | s, was last week's physical c | activity more, less, | |
| | or about the same (check only one)? | | PAR | Q (TYPE 4) | |
| | 3 About the same | SAME AS PAGE 72 | | | |
| In | terviewer: Please answer questions | below and note any com | ments on interview. | | |
| 5 | Were there any problems with the S \square_0 No \square_1 Yes | Seven-Day PAR interview? | | | |
| 6 | Do you think this was a valid Seven one No 1 Yes | -Day PAR interview? | | | |
| 7 | Were there any activities reported be □ No □ Yes | by the participant that you | don't know how to classify? | | |
| | | | | | |



PAGEID = 272

| Center Number: Participant Number: Participant's Initi | | | | | | | | |
|--|--------------------------------------|--------------------------------------|--------------------|--|--------------------------------------|--|--|--|
| 6-D | ay Food Record | | | | | | | |
| Com | plete below OR Not done → Specify | y reason (use Codelist b | elow): _ | Staff init | rials: First middle last | | | |
| | SAME AS PAGE | 73 | Replacement Values | | | | | |
| Day of DLW | Date of Record | Record Quality (check only one) | Day of DLW | FOODRCD (TYPE | Record Quality (check only one) | | | |
| 1 | / | 1 Reliable 2 Unreliable 3 Missing | 8 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | | | |
| 2 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | 9 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | | | |
| 3 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | 10 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | | | |
| 4 | | 1 Reliable 2 Unreliable 3 Missing | 11 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | | | |
| 5 | | 1 Reliable 2 Unreliable 3 Missing | 12 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | | | |
| 6 | / | 1 Reliable 2 Unreliable 3 Missing | 13 | / | ☐₁ Reliable ☐₂ Unreliable ☐₃ Missing | | | |
| | | | | | | | | |
| Not | Done Codelist: 1 Participant refused | 2 Clinician unable to ob | tain 3 | Insufficient time 4 Instrument failure | 5 Not required | | | |
| | | | | | | | | |



PAGEID = **273**

| | Center Number: Participant Number: Participant's Initials: first middle last |
|--------|---|
| V | O ₂ Max |
| 1 | |
| | OR Not done → Specify reason (use codelist below): — SAME AS PAGE 81 |
| 2 | At what time was the participant's last meal/snack eaten? |
| 3 | Rest ECG: Rhythm (check only one): \square_1 Sinus \square_2 Atrial fibrillation \square_{98} Other Ventricular conduction (check only one): \square_1 Normal \square_2 LBBB \square_3 RBBB |
| 4 | Heart rate (HR) data: Resting heart rate: bpm Age-predicted heart rate: bpm Heart rate (max): bpm |
| 5 | Reason(s) for termination of testing (check all that apply): Symptom limited (dyspnea, fatigue) Angina/ischemia++ → Complete all that apply: HR when true cardiac angina occurred: |
| 6 | Did frequent ventricular ectopy occur (e.g., \geq 7 PVCs/min, bi/tri-geminy, NSVT [\geq 3 beats])? \square_0 No \square_1 Yes \rightarrow If Yes: When did it occur (check all that apply)? \square During exercise \square During recovery |
| 7 8 | Peak VO_2 :mL/kg/minL/min |
| 9 | Exercise time: : seconds |
| 10 | Blood pressure at VO ₂ peak/VO ₂ max:/ mm Hg |
| 11 | Borg RPE score at VO ₂ peak/VO ₂ max: (6-20) |
| 12 | Peak RER: |
| 13 | VE at VO ₂ peak/VO ₂ max:L/min |

Not Done Codelist: 1 Participant refused 2 Clinician unable to obtain 3 Insufficient time 4 Instrument failure 5 Not required CALERIE PHASEE2 ANNOTATION V8.0 Send to DCRI Fori 24FEB2012



PAGEID = **274**

| | | umber: Part | icipant Numb | er: Particip | oant's Initials: | |
|--|--|--------------------|----------------|--|--|--|
| Outcomes Lo | | , | | OUTCMELD / | TVDE 4\DC | |
| Date and time samp | ole collection started:/_ No Display LMEAL | / | 00:00 | :_OUTCMELB (| 1 YPE 4)PS | |
| If a sample is not obt | Sample ained, indicate with a Not Done. | Sample Com | olete? | If Not Done, Reason (Use codelist below) | Staff Initials | |
| | Blood | □₀ No SAM □₁ Yes | | E AS PAGE 102 | first middle last | |
| Core Tempe | rature | | | | | |
| Staff Provide Date o Initials Sample Collection/Pro | | | 1 | lime of Sample ection/Procedure ADMIT (T | If Not Done, Reason (Use codelist below, | |
| | Start Date: | year | | Start Time : SAME A | , | |
| first middle last | Stop Date: | year | | Stop Time:00.00 to 23:59 | | |
| Inpatient Ad | lmission and Discha | rge | | | | |
| 1 Inpatient admis | sion date and time:/ | / | : | 23:59 | | |
| 2 Inpatient discha | ırge date and time:/ | month year | : | 23:59 | | |
| Not Done Codelist: | 1 Participant refused 2 Clinicia | n unable to obtain | 3 Insufficient | time 4 Instrument failure | 5 Not required | |



Delayed-type Hypersensitivity (DTH) DTHADM1 (TYPE 3) Was the DTH worksheet completed? U₀ No \square_1 Yes \rightarrow If Yes: Were any Exclusion criteria met? \square_0 No \rightarrow Proceed with test \square , Yes \rightarrow STOP. Do not administer test. SAME AS PAGE 85 Arm injected: ____, Right _____, Left DTH results: Note: For each reaction, measure two diameters in millimeters (mm). The first diameter is called the maximum diameter because the induration may not be in the shape of a circle. If the induration is an oval shape, first measure the long diameter and then the diameter perpendicular to it. Do not measure erythema. Reaction is considered positive if the average diameter is equal to or greater than 5 mm. DTHADM2 (TYPE 4)PS A = Largest diameter B = Second diameter perpendicular to A 24 Hour (@ Visit 4) 48 Hour (@ Visit 5) Antigen A (diameter) B (diameter) Read By: A (diameter) B (diameter) Read By: Normal saline ____ mm 2 Tetanus toxoid (TT) (check only one): Tetanus toxoid (Sanofi-____ mm | ___ mm Pasteur) ___₉₈ Other: __ Lot #: 3 Candida (check only one): first middle last first middle last Candin (AllerMed) (initials) (initials) _____ Other: _____ Lot #: 4 Trichophyton (check only onel: Trichophyton Allergic _____ mm | ___ _ __ mm Extract (AllerMed)

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

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98 Other: _____



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Center Number: ____ Participant Number: ____ Participant's Initials: first middle last

| Clinic Weight | | | | | | | | | |
|--|--|-----------------------------|--|-------------------|--|--|--|--|--|
| Weight date and time: _ OR Not done → Specify | day / | : 00 to 23:59 | Staff ini | tials: | | | | | |
| DATEHDR (TYPE 4) | | | | | | | | | |
| Clinic weight (if the two measurements are more than 0.1 kg apart, measure weight a third time): | | | | | | | | | |
| Weight 1: | Weight 1: ——·— kg SAME AS PAGE 4 WEIGHT (TYPE 4) | | | | | | | | |
| Weight 2: | kg | MOVED THE RMR | PANEL TO PAGE | = 276A | | | | | |
| Weight 3: kg | | | | | | | | | |
| Weight of gown: kg | | | | | | | | | |
| Outcomes Labs | | | | | | | | | |
| Date and time of last me | al:/ | | ÇUTCMELB (T | /PE 4)PS | | | | | |
| Date and time sample co | Date and time of last meal: | | | | | | | | |
| | Sample | Sample Complete? | If Not Done, Reason (Use codelist below) | Staff Initials | | | | | |
| Са | techolamines | □₀ No □₁ Yes | | first middle last | | | | | |
| | Blood | □₀ No □₁ Yes | | first middle last | | | | | |
| Oral glucos | e tolerance test (OGTT) | □₀ No □₁ Yes | | first middle last | | | | | |
| If a sample is not obtained, | indicate with a Not Done. | | | | | | | | |
| 24-hour Urine (| Collection | | | | | | | | |
| Total Volume Collected | Date of Sample Collection | Time of Sample Collectio | If Not Don Reason (Use codelist b | Staff Initials | | | | | |
| | Start Date: | Start Time: | ΨRINE24 (| ΓΥΡ Ε 3) | | | | | |
| | / | 00:00 to 23:59 | SAME AS I | PAGE 90 | | | | | |
| mL | Stop Date: | Stop Time: | | first middle fast | | | | | |
| | / | 00:00 to 23:59 | | | | | | | |
| Not Done Codelist: 1 Pa | rticipant refused 2 Clinician unable to | obtain 3 Insufficient time | 4 Instrument failure | 5 Not required | | | | | |



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Layout of data entry screen has changes also

Center Number: ___ Participant Number: ___ Participant's Initials: ___ __

| | | | | | first middle fast | | | |
|--|-------------------|---|-------------------------------------|--|-------------------|--|--|--|
| Sex Hormone | | | | | | | | |
| If Not Done → Specify reason (use code | list below) | SAME AS PAGE 90A | DATEHDR (TYPE 4) | | | | | |
| Contraception method (females only): | | None OR Check all that apply | OUTCME2 (TYPE 4) | | | | | |
| SAME AS PAGE 90A | | Record on Concomitant Medications page ○ Other → Specify (e.g., barrier, IUD): | | | | | | |
| Day 1 | | Date | Time | If Not Done, Reason (use codelist) | Staff Initials | | | |
| Day 1 of menses (females enly) | | | | | | | | |
| Date and time of last meal (males only | 1) | / | 00:00 to 23:59 | | | | | |
| Hormone level blood draw 1 (males o | nly) | | | | first middle last | | | |
| Hormone level blood draw 2 (formales of Progesterane level | o nly) | | | | | | | |
| Day 2 | | Date | Time | If Not Done, Reason (use codelist) | Staff Initials | | | |
| Date and time of last meal | | | | | | | | |
| Hormone level blood draw 3 (females of Progesterone level | only) | | | | | | | |
| Metabolic Rate | | | | | | | | |
| Sample | | Date of Collection | If Not Done, Re (Use codelist be | low) | f Initials | | | |
| Resting Metabolic Rate (RMR)—Visit 4 | SAME AS PAGE 153 | | KMR (1) | YPE 4)PS | first middle last | | | |
| Cart ID | | -003 (623-002) | | PBRC-016 (6234 PBRC-017 (6234 | • | | | |
| | | | | | | | | |
| Not Done Codelist: 1 Participant refused | 2 Clinic | cian unable to obtain 3 Insufficient ti | ime 4 Instrument | failure 5 Not r | equired | | | |

calerie Phase 2

Month 24 Submission

| P | AGEID | = 277 | | | | Center No | umber: _ | P | articipant | Number: _ | PAI | RHDR | articipant's (TYPE | Initials: | st middle last |
|---|---------|------------------------------|----------------|----------------|----------------------|---|----------|--------------------|------------|------------------------|------|----------------------|--------------------|-----------|----------------|
| Seven-Day Physical Activity Recall (PAR) | | | | | | | | | | | | | | | |
| Today's date: $_{\frac{day}{month}}$ / $_{\frac{year}{month}}$ Day (check only one): $_{\frac{day}{month}}$ Mon $_{\frac{day}{month}}$ Tues $_{\frac{day}{month}}$ Wed $_{\frac{day}{month}}$ Thurs $_{\frac{day}{month}}$ Sun $_{\frac{day}{month}}$ OR Not done \rightarrow Specify reason (use codelist below): $_{\frac{day}{month}}$ | | | | | | | | | | | | | | | |
| | | ou employed in the last seve | | | | → Skip to qu | | | | | | Interv | viewer init | tials: | middle last |
| 2 If Yes: Which days (check all that apply)? | | | | | | | | | | | | | | | |
| 3 | Which c | lays do you consider your w | | | | | Wed | | | | Sun | | | | |
| Day | | | Sleep Time | | | 110111111111111111111111111111111111111 | | rning (in minutes) | | Afternoon (in minutes) | | Evening (in minutes) | | | |
| # | Week | | In Bed | Up | Start | Stop | Mod. | Hard | Hard | Mod. | Hard | Hard | Mod. | Hard | Hard |
| 7 (yester- | | day month year | 00:00 to 23:59 | 00:00 to 23:59 | :: 00:00 to 23:59 | :: :: | | | | | PAF | CHT | (TYPE | 4)PS | |
| day) | | , | 00:00 to 23:59 | 00:00 to 23:59 | 00.00 10 20.07 | 0.001020.07 | | | | | | | | | |
| 6 | | / | 00:00 to 23:59 | 00:00 to 23:59 | :: | 00:00 to 23:59 | | | | | | | | | |
| | | | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | \vdash | | |
| 5 | | day month year | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
| | | | 00:00 to 23:59 | 00:00 to 23:59 | | | | | SAME | AS PAG | E 71 | | | | |
| 4 | | day month year | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | —— |
| 3 | | day month year | 00:00 to 23:59 | 00:00 to 23:59 | :: | :: | | | | | | | | | |
| | | day month year | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |
| 2 | | / | 00:00 to 23:59 | 00:00 to 23:59 | :: | : 00:00 to 23:59 | | | | | | | | | |
| | | , year | 00:00 to 23:59 | 00:00 to 23:59 | 70:00 to 20:09 | JV.0V 10 23.39 | | | | | | | igsquare | | |
| ¶ ? week | | | 00:00 to 23:59 | 00:00 to 23:59 | : | : | | | | | | | | | |
| ago) | | day month year | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | 00:00 to 23:59 | | | | | | | | | |



PAGEID = **278**

| | | Center Number: | Participant Number: | Participant's Initials: iniddle last |
|----|--|---------------------------|------------------------------|--------------------------------------|
| S | even-Day Physical Activ | vity Recall (PAR) | continued) | |
| 4 | Compared to your physical activity or about the same (check only one)? | • | ths, was last week's physica | l activity more, less, PARQ (TYPE 4) |
| | Less 3 About the same | SAME AS F | PAGE 72 | |
| In | terviewer: Please answer questions | s below and note any co | mments on interview. | |
| 5 | Were there any problems with the \square_0 No \square_1 Yes | Seven-Day PAR interviev | v? | |
| 6 | Do you think this was a valid Sever | n-Day PAR interview? | | |
| 7 | Were there any activities reported \square_0 No \square_1 Yes | by the participant that y | ou don't know how to classil | iy? |
| | | | | |



Participant's Initials: _

PAGEID = **279**

| Biopsy Labs | | | | | | | | |
|---------------|--------------------|--|-------------------|--|--|--|--|--|
| Sample | Date of Collection | If Not Done, Reason (Use codelist below) | Staff Initials | | | | | |
| Muscle biopsy | / | | first middle last | | | | | |
| Fat biopsy | | | first middle last | | | | | |

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

SAME AS PAGE 90

BIOPSY (TYPE 4)

Calerie Phase 2 FORM/BLOCK = ADVERSE EVENTS Signs, Symptoms and Adverse Events Log

AELOG (TYPE 4)R

PAGEID = 280

THIS IS A REPEATING PAGE

Center Number:

Participant Number: ___ __ ___

Participant's Initials:

| _ | Signs, Symptoms and Adverse Events Update form for each visit and mark corresponding additional box. Send copies of this form with each submission starting with baseline: TIMEPT <tutmpt> see</tutmpt> | | | | | | |
|-----------|--|--|--|--|---|---|--|
| В | Baseline 1 Baseline 2 Month 1 Month 3 Month 6 Month 9 Month 12 Month 18 Month 24 attached page for codelist | | | | | | |
| AE# AE | Adverse Event NUM <i:4></i:4> | Serious AE | Intensity INTEN <tute< th=""><th>Causality V></th><th>Action Taken Due to AE (check all that apply)</th><th>Outcome AEOUTCME<tuocme< th=""><th>Start/End Date OR Check if Continuing</th></tuocme<></th></tute<> | Causality V> | Action Taken Due to AE (check all that apply) | Outcome AEOUTCME <tuocme< th=""><th>Start/End Date OR Check if Continuing</th></tuocme<> | Start/End Date OR Check if Continuing |
| | AESPEC <v:100> AESER<</v:100> | □ ₀ No □ ₁ Yes* | ☐ ₁ Mild ☐ ₂ Moderate ☐ ₃ Severe | ☐ None ☐ Doubtful ☐ Possibly ☐ Probably ☐ Probably ☐ Very likely ☐ SE <tucaus></tucaus> | ALL <xyes> None</xyes> | ☐ 1 Still present and unchanged ☐ 2 Improving ☐ 3 Resolved ☐ 4 Resolved with sequelae ☐ 5 Death | Start Date: AESTRDT day month year End Date: AESTPDT day month year OR 1 Continuing AECONT XYES |
| | MEDRA | □ ₀ No □ ₁ Yes* | ☐ ₁ Mild ☐ ₂ Moderate ☐ ₃ Severe | ☐ ₁ None ☐ ₂ Doubtful ☐ ₃ Possibly ☐ ₄ Probably ☐ ₅ Very likely | □ 1 None ACNONE □ 2 Intervention temporarily TEMPD discontinued □ 3 Medical therapy red PERMD discontinued □ 4 Intervention permaneral PERMD discontinued □ 98 Other (specify): | Q□₃ Resolved □₄ Resolved with sequelae □₅ Death | Start Date: day month year End Date: day month year OR 1 Continuing |
| _ | MEDRIEXI < V:1100> MEDRCODE < V:8> WORKFLOW < V:5> CODETM < DATETIME: CONFLVL < V:2> MATCHES < V:4> CODER < V:20> | □ ₀ No □ ₁ Yes* | ☐ ₁ Mild ☐ ₂ Moderate ☐ ₃ Severe | ☐ None ☐ Doubtful ☐ Possibly ☐ Probably ☐ Very likely | ACOTHS | V:50> 1 Still present and unchanged 2 Improving 3 Resolved 4 Resolved with sequelae 5 Death | Start Date: day / month / year End Date: day / month / year OR |
| | | □ ₀ No □ ₁ Yes* | ☐ ₁ Mild ☐ ₂ Moderate ☐ ₃ Severe | ☐ ₁ None ☐ ₂ Doubtful ☐ ₃ Possibly ☐ ₄ Probably ☐ ₅ Very likely | ☐ 1 None ☐ 2 Intervention temporarily discontinued ☐ 3 Medical therapy required ☐ 4 Intervention permanently discontinued ☐ 98 Other (specify): | ☐ Still present and unchanged ☐ Improving ☐ Resolved ☐ Resolved with sequelae ☐ Death | Start Date: day / / / year End Date: day / onth / year OR |

*If Serious is Yes, submit expedited SAE form.

lity/incapacity CALERIE PHASE2 ANNOTATION V8.0 24FEB2012 alization

5 Congenital anomaly or birth defect

6 Other significant medical event

TUTMPT Codelist

- 1 = Baseline 1
- 2 = Baseline 2
- 3 = Month 1
- 4 = Month 3
- 5 = Month 6
- 6 = Month 9
- 7 = Month 12
- 8 = Month 18
- 9 = Month 24

Participant Number: ___ __ __

PAGEID = 281

Concomitant Medications Log

Participant's Initials: ______

| Medication | Start Date or ☑ if Pre-study | 6 Month 9 Month 12 Stop Date or ✓ if Continuing | Indication |
|---|--|--|------------------------------------|
| STUDYSUP <tumed> Study vitamin-mineral supplement</tumed> | SUPSTRDT | SUPSTPDT CONME | |
| 2 Study calcium supplement | Derivation for CONMED1 | Vitamins 90 day morth year Calcium 00 | HOCODE 0005301001 0751501001 |
| SEE PAGE 281A | or \square_1 Pre-study | day morth year OR 1 Continuing | IED2 (TYPE 4)R |
| DNUM <i:2> 4 CMED<v:110></v:110></i:2> | CMSTRDT day month year OR 1 Pre-study | CMSTPDT | MEDIND <v:110< td=""></v:110<> |
| 5 | CMPSTDY <xyes> day / morth / year OR 1 Pre-study</xyes> | CMEDCONT < XYES: day / morth / year OR | |
| WHODRUG_B2 WHONAME <v:80></v:80> | or D ₁ Pre-study | or \prod_1 Continuing | |
| WHOCODE <v:32> WORKFLOW <v:5> CODER <v:20></v:20></v:5></v:32> | or D ₁ Pre-study | or \prod_1 Continuing | |
| CODETM <datetime CONFLVL <v:2> MATCHES <v:4></v:4></v:2></datetime | or 1 Pre-study | or la Continuing | |
| WHODRUG_ATC_B2 | or the property of the state of | day morth year OR 1 Continuing | |
| ATCTERM <v:110> 10 ATCCODE<v:40> WORKFLO2<v:5></v:5></v:40></v:110> | day /_ morth /_ year OR 1 Pre-study | or | |
| CODETM2 < DATETIME CONFLVL2 < V:2 > MATCHES2 < V:4 > CODER2 < V:20 > | or 1 Pre-study | day / morth year OR 1 Continuing | |

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Send to DCRI For urham NC 27705



Concomitant Medications Log

PAGEID = 281+

| Center Number: | Participant Number: | Participant's Initials: | |
|----------------|---------------------|-------------------------|-------------------|
| | | | fines middle land |

| Concomitant Medications Log | | | | | | | |
|--|---------------------------------|---|------------------|--|--|--|--|
| Record any medications taken after start of baseline visit, including over-the-counter and prescription drugs, vitamins, supplements, and herbal medications. Update form for each visit and mark corresponding additional box. Send copies of this form with each submission starting with baseline: Baseline 1 Baseline 2 Month 1 Month 3 Month 6 Month 9 Month 12 Month 18 Month 24 | | | | | | | |
| Medication | Start Date or ☑ if Pre-study | Stop Date or ☑ if Continuing | Indication | | | | |
| 1 | or The Study | CON day // | MED2 (TYPE 4)R | | | | |
| 2 | or Pre-study | day / morth / year OR 1 Continuing | SAME AS PAGE 281 | | | | |
| 3 | or north year | or | | | | | |
| 4 | or D ₁ Pre-study | day / morth / year — OR □1 Continuing | | | | | |
| 5 | or north year | or _1 Continuing | | | | | |
| 6 | or | or \prod_1 Continuing | | | | | |
| 7 | or 1 Pre-study | day / morth year OR 1 Continuing | | | | | |
| 8 | or 1 Pre-study | day / morth / year OR 1 Continuing | | | | | |
| 9 | or 1 Pre-study | day morth year OR 1 Continuing | | | | | |
| 10 | or | day // | | | | | |
| 11 | or $\frac{1}{1}$ Pre-study | doy /— morth /— year — OR □₁ Continuing | | | | | |
| 12 | or Pre-study | day /- morth /- year | | | | | |

Page Numbering: Sequentially number each page in the right hand corner, i.e. 281+.1, 281+.2, 281+.3. Insert additional pages as needed.



Concomitant Medications Log

PAGEID = 281

CONMED1 (TYPE 4)PS

| | Study Calcium Supplement 1000 mg | | | | | | | | |
|---|--|------------|-----------------------------|--|--|--|--|--|--|
| | Medication STUDYSUP <tumed></tumed> | Start Date | Stop Date | | | | | | |
| 3 | = Study calcium supplement, 1000 mg | SUPSTRDT | ⊸SÚPSHPDT _{year} — | | | | | | |

SAME AS PAGE 281

Derivation for CONMED1

<u>WHOTERM</u> Calcium

WHOCODE 00751501001

calerie Phase 2

PAGEID = 282

THIS IS A REPEATING PAGE

Date received at DCRI Safety Surveillance

FORM/BLOCK = ADVERSE EVENTS Serious Adverse Fvent Form

| Report type: Initial SAETYPE <turptp> Initial SAETYPE<turptp> Center Num</turptp></turptp> | ber: | Participant Number: _ | Participant's Initials: |
|--|---|------------------------|--|
| SAE Details: | | Participant's Details: | |
| SAE Term (Medical Diagnosis): SAEDIAG <v:100> SAESTRDT SAE Onset Date:/</v:100> | Date of birth: | | |
| Serious Reporting Criteria: (check all that apply) Death DEATH ALL <xyes> Life-threatening LIFETHRT DISINCAP Persistent or significant disability or incapacity Prolonged or required hospitalization PRLGHOSF Congenital anomaly or birth defect CONGDEF Other significant event requiring medical and/or surgical intervention OTHRSIG</xyes> | Serious Reporting Criteria: (check all that apply) (check all that apply) (check all that apply) (check all that apply) (constitution of the significant disability or incapacity Prolonged or required hospitalization PRLGHOSP Congenital anomaly or birth defect CONGDEF Other significant event requiring medical and/or Causality Causality Causality Presistent or significant disability or incapacity Prolonged or required hospitalization A F | | Outcome (at time of report): (check only one) SAEOTCME <tuocme> □ Still present and unchanged □ Improving □ Resolved □ Peath → If Death: Date of death: DEATHDT/ □ Death → If Death: Date of death: NEDRA MEDRA MEDRA MEDRA MEDRA MEDRCODE<v:8> WORKFLOW<v:5> CODETM<datetime> CONFLVL<v:2></v:2></datetime></v:5></v:8></tuocme> |
| Action Taken with Study Intervention: (check all that a | pply) | | MATCHES <v:4></v:4> |
| None ACNONE Intervention temporarily discontinued → Complete an Medical therapy required ACMEDREQ Intervention permanently discontinued → Complete an ACPE Other (specify): ACOTHR ACOTHS | RMD nd fax the | Permanent Discontinua | |

ADDITIONAL PANEL ITEM ON PAGE 284.

Notify DCRI Safety Surveillance of the SAE within 24 hours after your knowledge

Fax SAE form to DCRI Safety Surveillance at 1-919-668-7138 or 1-866-668-7138

within 24 hours of initial notification



Date received at DCRI Safety Surveillance

Serious Adverse Event Form

| Report type: Initial Follow-up #: | Cent | er Number: _ | | Participant Number: | Par | ticipant's Initials: |
|--------------------------------------|----------------|----------------|---------------|---------------------|---|----------------------|
| Medical History (relevant to event): | | | | | | |
| THIS PAGE NOT ENTERED | | | | | | |
| Concomitant Medication (do not list | medication c | administered t | to treat this | s event): | | |
| Medication | Dose & Unit | Frequency | Route | Start Date | Continued | Stop Date |
| | | | | | □ ₀ No □ ₁ Yes | day month year |
| | | | | | □₀ No □₁ Yes | / |
| | | | | day month year | □₀ No □₁ Yes | day month year |
| | | | | day month year | □₀ No □₁ Yes | day month year |
| | | | | | □ ₀ No □ ₁ Yes | day month ywar |
| | | | | | □ ₀ No □ ₁ Yes | day month year |
| | | | | | □ ₀ No □ ₁ Yes | day month year |
| Relevant Lab Tests: | | | | | | |
| Test | | Date | | Value/Results | 1 | Normal Range |
| | / | month) | year | | | |
| | day / | | | | | |
| | | | | | | |
| | / | month / | year | | | |

Notify DCRI Safety Surveillance of the SAE within 24 hours after your knowledge

Fax SAE form to DCRI Safety Surveillance at (919) 668-7138 or 1-866-668-7138 within 24 hours of initial notification

2010 DCRI — Confidential



Date received at DCRI Safety Surveillance

CONTINUED FROM PAGE 282

Report type: Initial

Serious Adverse Event Form

| Follow-up #: Center Number: | Participant Number: Participant's Initials: |
|---|---|
| Please provide a brief summary of the event: | |
| SAESUMRY <v:150></v:150> | |
| | |
| | |
| Please describe the sequence of events including action taken, trea | tment given, hospital dates, etc.: |
| | |
| | |
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| | |
| NOT DATA | BASED |
| | |
| | |
| | |
| | |
| Information Source: | |
| Date level director and find of Events | Duta of this year out |
| Date Investigator notified of Event:/ | Date of this report:/ |
| Person completing form: | Phone number: () |
| PI name: | Fax number: () |
| PI signature: | Date of signature: |
| | |

Notify DCRI Safety Surveillance of the SAE within 24 hours after your knowledge

Fax SAE form to DCRI Safety Surveillance at (919) 668-7138 or 1-866-668-7138 within 24 hours of initial notification



Excessive Weight Loss Episode Report

PAGEID = 285 Participant Number: __ Participant's Initials: _

FORM/BLOCK = SURVEILLANCE

| | first middle last | | | | | |
|---|---------------------------------------|--|--|--|--|--|
| Excessive Weight Loss Episode | | | | | | |
| Excessive weight loss is defined as a BMI < 18.5 kg/m ² . This report is completed for each episod when the BMI level is first observed to be < 18.5 kg/m ² , and ends when the episode either resold discontinued from the CR intervention as a direct result of this episode. | ves or the participant is permanently | | | | | |
| , wc | GHTLOSS (TYPE 4) | | | | | |
| A Identifying information REPORTDT | | | | | | |
| 1 Date of initial report:/ | D | | | | | |
| B BMI below 18.5 kg/m² | | | | | | |
| 3 Date of threshold value:/ | All measurements <f:9:3></f:9:3> | | | | | |
| 4 Height: cm (from original measurement at Screening) 5 Weight: kg WEIGHT1 | | | | | | |
| 6 Calculated BMI: kg/m ² CALBMI1 | | | | | | |
| C Temporary Discontinuation If BMI < 18.5 kg/m², the participant is advised about the risks of excessive weight loss and is prescribed a diet plan with increased number of calories up to the baseline level for up to one month. TMPDIS <xyesno> 7 Was CR temporarily discontinued and a diet plan prescribed? □₀ No → If No: Indicate the reason why it was not temporarily discontinued: EXPLAIN<v:50> □₁ Yes → If Yes: Complete the Temporary Discontinuation from CR Intervention form and fax to Safety Surveillance immediately. Continue to section D below.</v:50></xyesno> | | | | | | |
| , | | | | | | |
| The CR intervention is only restarted if the BMI increases to 18.5 kg/m² or higher after one 8 Date of follow-up value: | month of treatment. | | | | | |
| 10 Calculated BMI:kg/m² CALBMI2 | | | | | | |
| E Permanent Discontinuation If BMI is still < 18.5 kg/m2 after one month of increased calorie intake, CR intervention is per | ermanently discontinued. | | | | | |
| 11 Was the participant permanently discontinued from the CR intervention? F □₀ No → If No: Indicate the reason CR was not permanently discontinued (chec | MI> | | | | | |
| | LAI LINOTTICV.302 | | | | | |
| Note that a participant is permanently discontinued from the CR intervent any point after the CR was restarted. If this happens, complete the Perma Intervention form. CALERIE PHASE2 ANNOTATION V8.0 24FE | nent Discontinuation from CR | | | | | |



Excessive Weight Loss Episode Report

| | | Center Number: | _ Participant Number: | P | artiapant's Initials: | first middle last |
|-----|-----------------------------------|-----------------------|-----------------------|--------|-----------------------|-------------------|
| E | xcessive Weight Loss Ep | isode (continued) | | | | |
| | | | | | | |
| F | Please provide a description of t | his episode including | actions taken: | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | THIS | PAGE NOT ENTE | RED | | | |
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| - 6 | tala Managaria Siamat | | | | | |
| 2 | tudy Manager's Signati | Jre | | | | |
| Si | gnature: | | | Date:/ | / | _ |
| | | | | day | north year | |
| | | | | | | |



Depression Episode Report

| | PAGEID = 287 | Center Number: | Participant Number: | Participant's Initials: first middle to |
|---|--|------------------------------|----------------------------------|--|
| D | epression Episode | | | |
| | epression is defined as a BDI score ≥ 20. To DI is ≥ 20, and ends when the episode eith | | | · . |
| | | | | EPRESS (TYPE 4) |
| A | I Date of initial report:/ | REPORTD | Т | |
| | 2 Name of person making this repo | | NOT DATABASED | |
| В | Initial Elevation in BDI Score ≥ 20 3 Date of initial elevation:/_ 4 BDI score: | | | |
| c | Repeat BDI Score The questionnaire is repeated in one was 5 Date of follow-up questionnaire: 6 BDI score: REF | / | PBDIDT | |
| D | Temporary Discontinuation If the repeat score is ≥ 20, the CR interven | ention is temporarily discor | ntinued and a participant is adv | rised to seek medical help outside of the |
| | study. | | TMPDIS< | :XYESNO> |
| | 7 Was the participant temporarily of | son CR was not tempora | rily discontinued (check only | one): TMPRSN <tubdi> on stop here; the episode has</tubdi> |
| | | resolved | | |
| | ☐ ₉₈ Other (speci | | form on the last page and s | |
| | | mporary Discontinuatio | n from CR Intervention form | and fax to Safety Surveillance |
| E | Follow-up BDI Score The questionnaire is repeated in one me 8 Date of follow-up questionnaire: | FLWUPD | Г | |
| | | day month year | | PANEL ITEMS NEXT |

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

PAGE



Depression Episode Report

| Depression Episode (continued) | |
|---|--|
| F Permanent Discontinuation If BDI score is ≥ 20 after one month of treatment, or a qualified mental health profession intervention will be permanently discontinued. 10 Was the participant permanently discontinued from the CR intervention? □₀ No → If No: Indicate why CR was not permanently discontinued (check □₁ BDI score returned below 20 PERMRSN <tue health="" indicated="" is="" it="" mental="" professional="" resume<="" safe="" th="" to="" □=""><th>PERMDIS<xyesno> only one): DEPR> EXPLAIN2<v:50> Intion form and fax to Safety Surveillance tion if a BDI score ≥ 20 occurs at any</v:50></xyesno></th></tue> | PERMDIS <xyesno> only one): DEPR> EXPLAIN2<v:50> Intion form and fax to Safety Surveillance tion if a BDI score ≥ 20 occurs at any</v:50></xyesno> |
| | |
| NOT DATABASED | |
| | |
| | |
| Study Manager's Signature | |
| Signature: | Date:/ |

Eating Disorder Episode Report

| | Center Number: | Participant Number: | Participant's Initials: first middle last |
|--|--|--|--|
| Eating Disorder Episode | | | |
| Eating disorders are defined in terms of score Acceptability Morph (BAM) and Interview fo and/or BAM indicate that there is an eating discontinued from the CR intervention. | r the Diagnosis of Eating Di | isorders—Fourth Version (IDED-IV). Re the episode either resolves or the pa | eporting starts when MAEDS |
| A Identifying information | SERORITA | | |
| 1 Date of initial report:/ | REPORTDT | NOT DATABACED | \neg |
| 2 Name of person making this repo | 38 | NOT DATABASED | |
| Please complete Section B and/or C BAM, or both. B Disorder Detected by the MAEDS the IDED-IV. | <u></u> | | |
| MAEDS Domain | f-score | MAEDS Domain | f-score |
| 3 Binge eating BINEAT | | 6 Purgative behavior | PURGE |
| 4 Restrictive eating RESEAT | | 7 Avoidance of forbidden fo | ods AVOID |
| | | 100 march 100 ma | |
| 5 Fear of fatness FEARFAT | | 8 Depression | DEPRESN |
| 5 Fear of fatness FEARFAT C Disorder Detected by the BAM A participant who (a) scores a t-score of it or (c) shows confirming acceptability of the 9 Was an alert issued for the curre 10 Was an alert issued for the ideal 11 Was there confirming acceptability | te extreme body size shown LL 3 < XYESNO> Int body size scale? | body size, (b) scores a t-score lower in the acceptability phase of the me CBSSCALE | than 30 on the ideal body size, asure is administered the IDED-IV. CBSCORE 1 Yes → If Yes: 1-score: IBSCORE 1 Yes → If Yes: 1-score: |

ADDITIONAL PANEL ITEMS NEXT **PAGE**



Eating Disorder Episode Report

CONTINUED FROM PAGE 289

Center Number: ___ _ Participant Number: ___ _ _

Participant's Initials: first middle last

| E | Eating Disorder Episode (continued) | | |
|-------|---|--|--|
| | E Permanent Discontinuation If a participant meets one or more of these diagnostic criteria, the CR intervention is permanently discontinued and a participant is advised to seek medical help outside of the study. 13 Was the participant permanently discontinued from the CR intervention? □₀ No → If No: Indicate why CR was not permanently discontinued (check only one): □₁ Did not meet diagnostic criteria for these eating disorders □₂₀ Other (specify): □₁ Yes → If Yes: Complete the Permanent Discontinuation from CR Intervention form and fax to Safety Surveillance immediately. | | |
| F | Please provide a description of this episode including actions taken: | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | NOT DATABACED | | |
| | NOT DATABASED | | |
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| | | | |
| | | | |
| | | | |
| ے | Sharks Manager (a. S.) | | |
|) | tudy Manager's Signature | | |
| Się | gnature: Date:/ | | |



Elevated Potassium Episode Report

PAGEID = 291

| | PAGEID = 291 | Center Number: | _ Participant Number | : | Participant's Initials: | middle fa |
|-----|---|--|---|---|---|-----------|
| E | levated Potassium Episo | de | | | | |
| rej | perkalemia is defined as an initial potassiun port is completed for each episode of hyper the particular the episode either resolves or the episode either episode episode either episode | rkalemia. Reporting start | s when the initial potas | sium level is gree | ater than 5.5 mEq/L., and en | |
| A | 1 Date of initial report:/ | REPORTD | T NOT DATABA | VATEK (T | YPE 4) | |
| В | Initial Elevation in Potassium Leve 3 Date of initial elevation:/_ 4 Potassium level: mEc | INELEVD | т | All measu | rements | |
| c | Follow-up Repeat Potassium Leve If the initial potassium level is between 5.3 | el | (inclusive), the test is r | <f:9:3></f:9:3> | | |
| | mEq/L, it is repeated within 48 hours. 5 Date of follow-up test: mEd 6 Potassium level: mEd | | MDT | | | |
| D | If the follow-up test is > 5.5 mEq/L, the Co to seek medical help outside of the study. 7 Was the participant temporarily d ☐ No → If No: Indicate the reas ☐ 1 Potassium retu ☐ 98 Other (specifing 1) Yes → If Yes: Complete the Test | iscontinued from the Con CR was not tempor orned to 5.5 mEq/L or lo | CR intervention? rarily discontinued (conver → If potassium in episode has in page, and state of the potassium in page, and state of the page, and state of th | MPDIS <xye 5.5="" heck="" in="" one):="" only="" ore="" partic<="" resolved.="" returned="" stop="" th="" the="" to=""><th>SNO> TMPRSN<tuelp! binder.<="" form="" here,="" ipant's="" l="" lower,="" meq="" on="" or="" sign="" th="" the="" then=""><th>VI></th></tuelp!></th></xye> | SNO> TMPRSN <tuelp! binder.<="" form="" here,="" ipant's="" l="" lower,="" meq="" on="" or="" sign="" th="" the="" then=""><th>VI></th></tuelp!> | VI> |
| E | Follow-up Potassium Level The CR intervention will only be restarted 8 Date of follow-up test:/ 9 Potassium level: mEa | | PDT | | nth of treatment. | |



Elevated Potassium Episode Report

| CONTINUED FROM PAGE 291 | enter Number: | Participant Number: | Participant's Initials: | first middle last |
|-------------------------|---------------|---------------------|-------------------------|-------------------|
| | • | | | test media last |

| Elevated Potassium Episode (continu | ued) | | |
|---|--|---|----------------------------|
| F Permanent Discontinuation If potassium level is still elevated above 5.0 mEq/L after 10 Was the participant permanently discontinued □ No → If No: Indicate why CR was not permanently discontinued □ No → If No: Indicate why CR was not permanently discontinued to 5.0 m □ No → If No: Indicate why CR was not permanently elevation. □ No → If Yes: Complete the Permanent Discontinuation. | from the CR intervention? manently discontinued (che EQ/L or lower EXPLAIN2 | PERMDIS <xyesi 2<v:50="" eck="" one):="" only="" permrs=""></xyesi> | NO> N <tuelvn></tuelvn> |
| immediately. Note that a participant is permanently discontinhigher occurs at any point after the CR was rest from CR Intervention form. G Please provide a description of this episode | arted. If this happens, (| complete the Permanent D | |
| | | | |
| N(| OT DATABASED | | |
| | | | |
| | | | |
| Study Manager's Signature: | | | |
| Signature: | | Date:/// | year |



Anemia Episode Report

PAGEID = 293

| | PAGEID = 293 | Center Nun | ber: | Participant Number | | Participant's Initials: first middle last |
|-----|---|---|-----------------|-------------------------------|--|---|
| A | nemia Episode | | | | | |
| a (| confirmatory value satisfying | ase in hemoglobin and/or he g the same criteria. Reporting permanently discontinued fro | starts when | the initial value is o | | 324 15 |
| A | Identifying Informat | | | | EMIA1 (TYPE | 4) |
| | 2 Name of person mo | aking this report: NOT B according to whether | DATABAS | SED | All measurem <f:9:3> ematocrit was be</f:9:3> | |
| nc | normal. | | | | | |
| В | Value(s) Below the L 3 Date of lab test: | ower Limit of Normal: | LABDT | | | |
| | | Value | 3 | Lower Limit o | f Normal (LLN) | ABOUT THENOS |
| | 4 Hemoglobin: | HGLOB1 | - | | | □ ₀ No □ ₁ Yes |
| | 5 Hematocrit: | HCRIT1 | | | GLOBLI | |
| | 6 RBC: | RBC1 | | | CRITLL | |
| | 7 Iron level: | IRON1 | | | RBCLLN | 1 \square_0 No \square_1 Yes |
| c | | ii torti | | | IRONLL | .N1 |
| | | | | | | |
| | | | | | | |
| | BLCI | RITDT | | BLCRIT | | |
| | FL | JCRITDT | | FLUPCRIT | N | IOT DATABASED |
| D | Repeat Test: The hematology panel is | repeated in two weeks. The i | ron level is a | DECREASE | | |
| - | 11 Date of repeat lab t | | year | | | |
| | | Value | REPT | B D ower Limit o | f Normal (LLN) | Below LLN? |
| | 12 Hemoglobin: | | | | | ALL KXYESNQ> |
| ſ | 13 Hematocrit: | | | | | □₀ No □₁ Yes |
| | 14 RBC: | HGLOB2 | | | GLOBLLN: | □0 140 □1 162 |
| Ī | 15 Iron level: | HCRIT2 | | | CRITLLN2 | |
| | If the repeated test confin Nevertheless, s/he continu | RBC2 ms the previous findings, a p IRON2 ues the CR intervention. | articipant is c | advised to seek medic | RBCLLN2 al help outside of the IRONLLN2 | study. |



Anemia Episode Report

PAGEID = 294

| | PAGEID = 294 | Center Number: | Participant Number: | P | articipant's Initials: first middle last |
|---|--|---|--|--|--|
| A | Anemia Episode (continued) | | | | |
| E | Medical Help Outside the Study: | | | ANE | MIA2 (TYPE 4) |
| | 16 Was the participant advised to see | k medical help outside | the study? MEDHEL | P <xyesn< th=""><th>10></th></xyesn<> | 10> |
| | | | | | |
| | | anel and iron levels retu | rned to acceptable values $ ightarrow$ | | |
| | HELI | PRSN <tuhelp></tuhelp> | | episode has | reptable values, then the resolved. Stop here, n on the last page, and |
| | |): HLPOTHS | P <v:50></v:50> | store in the p | participant's binder. |
| | | atient was advised: _ | day month year | | |
| _ | | | , | | |
| F | One Month Follow-up Test If the hematology and iron levels do not | return to acceptable valu | es the hematology panel an | d iron levels ar | re repeated one month after |
| | the treatment was initiated. | | es, me nemalology panel and TH1DT | a non levels al | e repealed one monin dher |
| | 17 Date of one month follow-up lab to | | | | |
| | All measurements | day month | уват | | ALL <xyesno></xyesno> |
| | <f:9:3></f:9:3> | Value | Lower Limit of Norn | nal (LLN) | Below LLN? |
| | 18 Hemoglobin: HGLOB3 | | GI | LOBLLN3 | □₀ No □₁ Yes |
| | 19 Hematocrit: HCRIT3 | | CI | RITLLN3 | □₀ No □₁ Yes |
| | 20 RBC: RBC3 | | RI | BCLLN3 | □₀ No □₁ Yes |
| | 21 Iron level: IRON3 | | IR | ONLLN3 | □₀ No □₁ Yes |
| G | If anemia is not improving or worsens, the 22 Was the participant temporarily d □ No → If No: Indicate the reas □ Hemoglobin p □ Solution of the period | iscontinued from the Coon why CR was not tendered and iron levels returned TMPRS EXPLAIN <v< th=""><th>R intervention? TMPDIS mporarily discontinued (che rned to acceptable values — N<tuanep> 7:50></tuanep></th><th>eck only one): If the hemogoreturn to acception to the form on forward to the with the next</th><th>globin and iron levels ceptable levels, the resolved. Stop here, sign the last page, and the coordinating center at batch of data forms.</th></v<> | R intervention? TMPDIS mporarily discontinued (che rned to acceptable values — N <tuanep> 7:50></tuanep> | eck only one): If the hemogoreturn to acception to the form on forward to the with the next | globin and iron levels ceptable levels, the resolved. Stop here, sign the last page, and the coordinating center at batch of data forms. |
| | | | | | |



Anemia Episode Report

PAGEID = 295

| | PAGEID = 295 | Center Number: | Participant Number: | Participant's Initials: $\frac{1}{first} \frac{1}{middle} \frac{1}{last}$ |
|----|--|---|---|---|
| A | nemia Episode | (continued) | | |
| Н | Two Month Follow-u | p Value | ANEMIA | A3 (TYPE 4) |
| | If anemia is not improving is permanently discontinu | | on was temporarily discontinued for one mor | nth, the intervention |
| | 23 Date of two month | follow-up lab test:/ _{month} /_ | FUMTH2DT | |
| | | day month | учот | ALL <xyesno></xyesno> |
| | | Value | Lower Limit of Normal (LLN) | Below LLN? |
| | 24 Hemoglobin: | HGLOB4 | GLOBLLN4 | □₀ No □₁ Yes |
| | 25 Hematocrit: | HCRIT4 | CRITLLN4 | □₀ No □₁ Yes |
| | 26 RBC: | RBC4 | RBCLLN4 | □₀ No □₁ Yes |
| | 27 Iron level: | IRON4 | IRONLLN4 | □ ₀ No □ ₁ Yes |
| | | All measurements <f:9:3></f:9:3> | | |
| ı | Permanent Disconti | nvatio <u>h</u> | | |
| | | | CR intervention? PERMDIS <xye< th=""><th></th></xye<> | |
| | □ _o No → If No: In | dicate the reason why CR was not p | ermanently discontinued (check only one | : SN <tuaneq></tuaneq> |
| | |] Hemoglobin panel and iron levels ret Hemoglobin panel and iron levels ret Hemoglobin panel Hemoglobin panel | EXPLAIN2 <v:50></v:50> | ONCTOANLES |
| | | | ntinuation from CR Intervention form an | d fax to Safety |
| | | urveillance immediately. | | , |
| J | Please provide a de | scription of this episode includin | ng actions taken: | |
| | • | | | |
| | | | | |
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| | | NOT D | ATABASED | |
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| | | | | |
| | | | | |
| S | tudy Manager' | s Signature: | | |
| | | | N / | , |
| Si | gnature: | | | month year |
| | | | | |



Ventricular Ischemia Episode Report

PAGEID = 296

| | PAGEID = 296 | Center Number: | Participant Number: | Participant's Initials: first middle last |
|----|--|--|--|--|
| V | /entricular Ischemia Episo | de | | |
| wh | his report is completed if an episode of ventrice when it is first observed, and ends when the epi R intervention. | | | |
| A | Identifying information | | | |
| | 1 Date of initial report:/ | _/REPOF | RTDT | |
| | 2 Name of person making this report | : | NOT DATABASEI | D |
| В | Date when the ventricular ischemic | ı was observed MAXDT | | |
| C | Temporary Discontinuation The CR intervention is temporarily discontinuated a Was CR temporarily discontinued a □ No → If No: Indicate the reason | ued and a stress ima nd a stress imaging | study ordered? TMF | PDIS <xyesno></xyesno> |
| | ☐ ₁ Yes → If Yes: Complete the Tem immediately. Cont | porary Discontinuc | | form and fax to Safety Surveillance |
| D | If a stress imaging Study If a stress imaging study confirms presence will follow all other study procedures to the 5 Date of study:/ | study end. STRES | SDT | permanently discontinued and a participant |
| | □- No | EMIA <xyesno< th=""><th></th><th></th></xyesno<> | | |
| E | Permanent Discontinuation | | | |
| | 7 Was the participant permanently di □ No → If No: Indicate the reason □ The study did no □ No → If Yes: Complete the Permit immediately. | n CR was not permoted confirm the present: | anently discontinued: ce of ventricular ischemia. EXPLAIN2 <v:150></v:150> | PERMRSN <tuvent></tuvent> |



Ventricular Ischemia Episode Report

| | Center Number: | Participant Number: | Participant's Initials: | first middle last |
|----------------------------|-----------------------------|---------------------|-------------------------|-------------------|
| Ventricular Ischemi | a Episode (continued) | | | |
| | | | | |
| F Please provide details o | t ECG tindings including ac | tions taken: | | |
| | | | | |
| | | | | |
| | THIS PAGE NOT EN | TERED | | |
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| | | | | |
| | - | | | |
| Study Manager's S | ignature: | | | |
| Signature: | | Date | :/ | - |
| | | | | |



Phase 2

Temporary Discontinuation from CR Intervention

DISCTYPE<TURPTP>

| ٠ | | | |
|---|------------|---------|-----------|
| | Check one: | Initial | Follow-up |

mber: ___ Participant Number: ___

Participant's Initials:

| first | middle | fast |
|-------|--------|------|

| Τe | Temporary Discontinuation | | | | | | | | |
|-----|---|-----------------------------|--------------|---------------|--|---|----------------|--|--|
| 1 2 | day month year TEMPONATUTEMPS | | | | | | | | |
| | if second level is above 5.5 mEq/L | | | | | | | | |
| Pa | rticipant's Details: | | | | | | | | |
| | te of birth:/ _{north} / nder: Male Female | year | | Wei | ght: cm ght: kg (if applicable): | | | | |
| Rel | evant Medical History: | | | | | | | | |
| | | | | | | | | | |
| Rel | evant Concomitant Medication (| do not list me | dication adn | ninistered to | o treat this event): | | | | |
| | Medication | Dose & Unit | Frequency | Route | Start Date | Continued | Stop Date | | |
| | | | | | | O No | day month year | | |
| | | | | | day month year | □ ₀ No □ ₁ Yes | day month year | | |
| | | | | | day month year | □ ₀ No □ ₁ Yes | day month year | | |
| Rel | evant Lab Tests: | | | | | | | | |
| | Test | | Date | | Value/Results | ı | Normal Range | | |
| | | /ADDITIONAL PANEL ITEM NEXT | | | | | | | |
| | | / | month | учат | PAGE | | | | |
| | | / | month 1 | учог | | | | | |
| | | / | month | year | | | | | |

Fax to Safety Surveillance at 1-866-668-7138



Temporary Discontinuation from CR Intervention

CONTINUED FROM PAGE 298 Genter Number: _____ Participant Number: _____ Participant's Initials:

| | Total | middle last |
|------------------------------------|---|-------------|
| Temporary Discontin | uation (continued) | |
| Please describe any additional act | on taken (e.g., observation or seek medical attention outside study): | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | NOT DATABASED | |
| | | |
| | | |
| | | |
| | | |
| Intervention Resump | tion | |
| | | |
| | Fill out Permanent Discontinuation from CR Intervention form | |
| ir res | : Date intervention was resumed:/ | |
| Investigator's Signat | ure | |
| | | |
| Investigator: | signature Date:/ | - |
| 1 | | |



Permanent Discontinuation from CR Intervention

Center Number: ____ Participant Number: ___ Participant's Initials: ____

PAGEID = 300

| Pe | ermanent Discontinuation |
|-----|--|
| 1 | Date of permanent discontinuation://PRMDISDT PERMRSN <tuperm> PERMDISC (TYPE 1)</tuperm> |
| 2 | Reason(s) for discontinuation (check only one): |
| | □ 1 Persistent potassium level > 5.0 mEq/L resistant to one month of treatment □ 2 Persistent potassium level ≥ 5.5 mEq/L after CR was temporarily discontinued and restarted |
| | 3 Persistent anemia (anemia still not improving or worsening one month after temporary discontinuation) |
| | Ventricular ischemia confirmed by stress image |
| | \square_5 Decrease in BMD at the hip or spine of 5% or greater from baseline at any time during first 12 months of CR |
| | $\square_{\rm 6}$ Decrease in BMD at the hip or spine of 10% or greater from baseline at any time during months 12–24 of CR |
| | |
| | a Eating disorder (including anorexia nervosa, bulimia nervosa or binge eating OR experiencing a sub-threshold eating disorder) |
| | Gruther decrease in BMI after 1 month of increase calorie intake OR temporary discontinuation of CR intervention OR persistent |
| | decrease in BMI (< 18.5) after CR intervention restarted |
| | \square_{10} rsychiatric disorder (including severe depression) \square_{11} Reoccurrence of moderate depression (BDI still > 20) after CR intervention restarted OR moderate depression that is not improving |
| | or is worsening (BDI ≥ 30) after temporary discontinuation of CR intervention |
| | 12 Major illness or disease (e.g., cancer) |
| | \square_{13} Trauma requiring prolonged hospitalization or bed rest for more than one month |
| | |
| | 15 Pregnancy (women only) |
| | |
| | PERSONAL <v:50> Personal reasons (specify): PERMOTHR<v:50></v:50></v:50> |
| | |
| Pai | ticipant's Details: |
| Da | re of birth: / / Height: cm |
| Ge | nder: Male Female Weight:kg |
| | BMI (if applicable): |
| Rel | evant Medical History: |
| | NOT DATABASED |
| | |
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Permanent Discontinuation from CR Intervention

Center Number: ___ Participant Number: ___ Participant's Initials: ___ __

| | | | | | | first middle fast | | | | |
|--|--------------------------------|----------------|------------|-------------------------------|---|-------------------|--|--|--|--|
| Permanent Discontinuation (continued) | | | | | | | | | | |
| Relevant Concomitant Medication (do not list medication administered to treat this event): | | | | | | | | | | |
| Medication | Dose & Unit Frequency Route | | | Start Date | Continued | Stop Date | | | | |
| | | | | | □ ₀ No □ ₁ Yes | / | | | | |
| | | | | day month year | □₀ No □₁ Yes | / | | | | |
| | | | | day month year | □ ₀ No □ ₁ Yes | | | | | |
| Relevant Lab Tests: | THIS | S PAGE N | IOT ENT | ΓERED | | | | | | |
| Test | | Date | | Value/Results | | Normal Range | | | | |
| | / | | | | | | | | | |
| | / | / | year | | | | | | | |
| | / | month / | учат | | | | | | | |
| | / | / | увот | | | | | | | |
| Please describe any additional action | on taken (e. | g., observatio | on or seek | medical attention outside stu | dy): | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| Investigator's Signatu | Jre | | | | | | | | | |
| | | | | | | | | | | |
| Investigator: | | signature | | Dat | e:/ | month year | | | | |

CALERIE PHASE2 ANNOTATION V4.012JUN2008

FORM/BLOCK = STUDY COMPLETION

calerie Phase 2

Study Completion/ Early Discontinuation of Study Evaluation

PAGEID = 302

| PAGEID = 302 | Center Number: Participant Number: | : Participant's Initials: indele tast |
|---|--|---------------------------------------|
| Completion/Early Discon | tinuation | |
| Did the participant complete the studion of the participant complete the studion of the prima o | ary reason for discontinuation (check only one) REASON <tuend></tuend> | (YESNO> : STDYCOMP (TYPE 1) |
| □ ₄ Death → Date • Co • Co • Re | → Complete Signs, Symptoms and Adverse E • If serious adverse event, complete Serio • of death:/// | s Log |
| □₁ Yes | | |

Durham NC

calerie Phase 2

FORM/BLOCK = HOME WEIGHT LOG

THIS IS A REPEATING PAGE

| Completed | by | Calerie staff: | |
|-------------------|----|--------------------|---------------------|
| Baseline Baseline | | 6 Months 12 Months | 18 Months 24 Months |

HWGHLOG1 (TYPE 4)

PAGEID = 303

TIMEPT<TUTMPT>
Center Number: ____ Participant Number: ____ Participant's Initials:

| Daily Home W | eight Log | | | | | | | | | |
|--|---------------|------------------------|-----------------------|--------------|------------------------------|-----------------------------|--|--|--|--|
| Were you issued a new scale? □ ₀ No □ ₁ Yes → If Yes: Date first used: □ _{month} Used: □ _{year} Serial no.: <u>SER</u> IALNO <v:30></v:30> | | | | | | | | | | |
| | | | | | | | | | | |
| Day of week: | Day of week: | Day of week: | Day of week: | Day of week: | Day of week: HWGHLOG2 (TY | Day of week: PE-4)R | | | | |
| Date: | Date: | Date: HWLOGDT day year | Date: | Date: | Date: | Date: | | | | |
| Time: 1 AM 2 PM -: 2 PM | Time:1 AM PM: | Time: 1 1 M 2 PM | Time: | Time: AM PM | Time: | Time: AM PM | | | | |
| Weight: | Weight: lb | Weight: | NOT DATABASED Weight: | Weight: | Weight: b | Weight: | | | | |
| | | HWEIGHT | | | | Check scale memory | | | | |
| | | <f:9:3></f:9:3> | | | | | | | | |
| Day of week: | Day of week: | Day of week: | Day of week: | Day of week: | Day of week: | Day of week: | | | | |
| Date: | Date: | Date: | Date: | Date: | Date: | Date: | | | | |
| Time: 1 AM 2 PM | Time: AM | Time: | Time: 1 AM 2 PM | Time: | Time: | Time: | | | | |
| Weight: | Weight: | Weight: | Weight: | Weight: | Weight: | Weight: | | | | |
| lb | lb | Ib | lb | Ib | lb | lb | | | | |
| | I . | 1 | 1 | ı | | , and an addition in come a | | | | |



FORM/BLOCK = PROTOCOL DEVIATION

Protocol Deviation

THIS IS A REPEATING PAGE PAGEID = 304

| PAGEID = 304 | Center Number: | Participant Number: | Participant's Initials: iniddle last |
|--|----------------------------|----------------------------------|--------------------------------------|
| Protocol Deviation | | | |
| Please indicate below any deviations fr Check all that apply (one participant per | | l taken for this participant. PD | EVIATE (TYPE 4)R |
| Baseline 1 Baseline 2 Month | n 1 | | h 12 Month 18 Month 24 |
| Date of deviation:/ | DEVDT ALL <xyes></xyes> | | TIMEPT <tutmpt></tutmpt> |
| ☐ Informed Consent CONSENT | | ☐ Study/laboratory procedure | es (specify): |
| ☐ Inclusion/Exclusion criteria INEXCL | | Participant non-fasting NC | DNFAST |
| Randomization/treatment assignment R | | Participant safety (specify): S | AFETY SAFEXPLN <v:50></v:50> |
| Concomitant Medications CONMED |) | Other (specify): OTHE | R OTHEREXP <v:50></v:50> |
| Brief explanation of deviation: | /EXPLN <v:150></v:150> | | |
| | | | |
| Baseline 1 Baseline 2 Mont | h 1 Month 3 | Month 6 Month 9 Mont | th 12 Month 18 Month 24 |
| Date of deviation:/ | year | | |
| ☐ Informed Consent | | Study/laboratory procedur | es (specify): |
| ☐ Inclusion/Exclusion criteria | | Participant non-fasting | |
| Randomization/treatment assignment | | Participant safety (specify): | |
| Concomitant Medications | | Other (specify): | |
| Brief explanation of deviation: | | | |
| | | | |

| Submission date: | / | / | Moste | / | / | Note | /_ | /_ | уеаг |
|------------------|---|---|-------|---|---|------|----|----|------|

Participant non-fasting

Other (specify):

Study/laboratory procedures (specify): ______

Participant safety (specify):

CALERIE PHASE2 ANNOTATION V8.0 24FEB2012

Baseline 1 Baseline 2 Month 1 Month 3 Month 6 Month 9 Month 12 Month 18 Month 24

☐ Informed Consent

Inclusion/Exclusion criteria

Concomitant Medications

Randomization/treatment assignment

Brief explanation of deviation: ___

Date of deviation: $___{day}$ / $___{month}$ / $___{year}$

PROTOCOL = CALERIE_PHASE2 STUDYBOOK = END OF CR SURVEY FORM = SURVEY



| Center Number | Participant Number |
|---------------|--------------------|
|---------------|--------------------|

End of CR Survey

CALSRVY (TYPE 1)

| | | | T | 1 | | | | |
|--|-------------------|-------|-------------------|-------------------------------------|----------------------|---------------|----------------------|-------------------|
| I was helped in following my CR prescription by | Strongly Agree | Agree | Agree Somewhat | Neither Agree Nor Disagree | Disagree Somewhat | Disagree | Strongly Disagree | Not Applicable |
| 1feeling prepared by what I was told about the intervention requirements before I started the study. PRI | 1 EREQ | 2 | ALL< | TUTOOL> | 5 | 6 | 7 | 0 |
| 2being provided my meals during the in-feeding period MEA | 1 LS | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 3trying the Mediterranean diet during the in-feeding period. | DIET | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 4trying the Low Glycemic diet during the in-feeding period. LO | 1 WGLYC | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 5trying the Low-fat High fiber diet during the in-feeding period. LOW | 1 FAT | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 6being trained on portion sizes during the first few weeks of the study. | 1 TION | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 7 using a system (like HMR) to memorize estimated calories. HMR | 1 SYS | 2 | 3 CALERIE PHA | 4 | 5 ATION V8 0 24 | 6 4FFB2012 | 7 | 0 |



Center Number __ _ Participant Number __ _ _ _

| I was helped in following my CR prescription by | Strongly Agree | Agree | Agree Somewhat | Neither Agree Nor Disagree | Disagree Somewhat | Disagree | Strongly Disagree | Not Applicable |
|--|-------------------|-------|-------------------|-------------------------------------|----------------------|----------|----------------------|-------------------|
| 8being provided recipes by the staff. RECIP | 1 ES | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| | 1 EMEA | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 10changing which food groups I include in my meals and snacks. | 1 ODCHG | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 11changing my eating patterns (how many times I eat a day). EATP | 1 ATT | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 12trying to use a Volumetrics approach (i.e., eating low- calorie foods of high volume), in order to feel fuller on my calorie prescription. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 13weighing in at my sessions. | 1 GHIN | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 14weighing myself at home. | 1 WGT | 2 | 3 | 4 | 5 | 6 | 7 | 0 |



Center Number __ _ Participant Number __ _ _ _ _

| I was helped in following my CR prescription by | Strongly Agree | Agree | Agree Somewhat | Neither Agree Nor Disagree | Disagree Somewhat | Disagree | Strongly Disagree | Not Applicable |
|---|-------------------|-------|-------------------|-------------------------------------|----------------------|----------|----------------------|-------------------|
| 15using the weight zone graph. WGT | 1 GRPH | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 16self- monitoring my calorie intake using a PDA. U | 1 SEPDA | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 17self- monitoring my calorie intake using a computer program. COI | 1 MPUTR | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 18self- monitoring my calorie intake using a paper record. | 1 APEREC | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 19individual sessions with my counselors. | 1 UNSLR | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 20written materials and handouts I received during individual sessions. | 1 ANDOUT | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 21having extra contacts by phone with my counselors.X | 1 TRPHON | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 22having extra contacts by email with my counselors. | TREMAI | 2 | 3 | 4 | 5 | 6 | 7 | 0 |



Center Number __ _ Participant Number __ _ _ _

| I was helped in following my CR prescription by | Strongly Agree | Agree | Agree Somewhat | Neither Agree Nor Disagree | Disagree Somewhat | Disagree | Strongly Disagree | Not Applicable |
|--|-------------------|-------|-------------------|-------------------------------------|----------------------|----------|----------------------|-------------------|
| 23 having extra contacts in-person with my counselors IN | 1 PRSON | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 24attending group sessions. | 1 PSESS | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 25written materials and handouts I received at group sessions. | 1 GRPHAND | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 26using behavioral contracts with my counselors. | 1 BEHAVE | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 27seeking social support of family or friends. SOC | 1 CSUPP | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 28being provided meal replacements. | 1 REPLACE | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 29decreasing the frequency of eating out. | 1 ATOUT | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 30increasing fiber in my diet. | 1 HFIB | 2 | 3 | 4 | 5 | 6 | 7 | 0 |



Center Number __ _ Participant Number __ _ _ _

| I was helped in following my CR prescription by | Strongly Agree | Agree | Agree Somewhat | Neither Agree Nor Disagree | Disagree Somewhat | Disagree | Strongly Disagree | Not Applicable |
|---|-------------------|-------|-------------------|-------------------------------------|----------------------|----------|----------------------|-------------------|
| 31returning to in-feeding later in the study (after the first in-feeding) | 1 NFEED | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 32having flexible options and strategies to assist my CR (instead of one structured program for everyone). | 1 FLEXOPT | 2 | 3 | 4 | 5 | 6 | 7 | 0 |
| 33being given some of my results during the 2 years, such as my total calories expended and how it related to my CR goal. | CRGOAL | 2 | 3 | 4 | 5 | 6 | 7 | 0 |



| Center Number | Participant Number | | |
|---------------|--------------------|------|------|
| | | | |

Now that you have finished the CALERIE trial, you may or may not choose to continue to follow a CR diet on your own.

Based on how you feel now, please answer these questions about your diet behavior after you finish CALERIE.

| | Strongly Agree | Agree | Agree Somewhat | Neither Agree Nor Disagree | Disagree Somewhat | Disagree | Strongly Disagree |
|--|-------------------|-------|-------------------|----------------------------------|----------------------|----------|----------------------|
| 34. After leaving CALERIE, I will continue to follow a CR diet. | POSTCR | 2 | 3 | 4 | 5 | 6 | 7 |

| | To A Great Extent | Somewhat | Undecided | Very Little | Not At All |
|---|----------------------------|----------|-----------|-------------|------------|
| 35. I plan to continue to follow my current level of CR | 1 LEVEL <tulev></tulev> | 2 | 3 | 4 | 5 |