5. SCREENING PROCEDURES

5.1 Summary of Screening Activities

The screening procedure is designed to determine eligibility of possible study participants over the course of three visits. During these visits the participant will complete a series of simple physiological tests, general questionnaires and psychological measurements. Anyone interested in the study and deemed eligible based on a brief phone interview will be scheduled for an initial screening visit. During screening, participants will be given detailed information regarding study requirements. The goal of screening is to determine eligibility and to give the participant a thorough understanding of the study requirements. A careful evaluation of whether a participant will be able to handle the physical and psychological demands as well as the time commitment is also completed.

After a volunteer is deemed eligible, they will be offered the opportunity to participate in the study. The first baseline visit is scheduled at this point and randomization occurs following the completion of all baseline measurements.

5.2 Inclusion and Exclusion Criteria

To be eligible for the study, volunteers must satisfy the following:

Inclusion criteria

- Age must be between 21 and 50 years of age (inclusive) for men
- Age must be between 21 and 47 years of age (inclusive) for women
- Female participants must agree to use acceptable method of contraception (barrier method, oral contraceptive, intrauterine device or similar hormone releasing agents) and be willing to continue using such a method while enrolled in this study. This must be documented and periodically assess by study staff for compliance for the duration of this study
- Body mass index (BMI) must be greater than or equal to 22.0 kg/m^2 and less than 28.0 kg/m^2. CALERIE will evaluate its degree of success in attracting participants using this lower BMI range and may elect to raise the upper limit if deemed necessary for adequate recruitment.

Exclusion Criteria

Volunteers will be excluded either during the phone interview or later in the screening process if they meet any of the criteria listed below:

Medical Exclusion Criteria

- History or clinical manifestation of cardiovascular disease or an elevated blood pressure (greater than 140/90 mm Hg)
- Abnormal resting ECG demonstrating: Type II second or third degree heart block; ventricular ischemia; left bundle branch block, cardiac hypertrophy by any criteria, QRS complex > 100 ms in duration; abnormal QTc interval,

- supra-ventricular tachycardia of any type but not including APC's, or ventricular arrhythmia of any type (including VPC's more than 60 per minute)
- History or clinical manifestation of diabetes
- History or clinical manifestation of cholelithiasis
- History or clinical manifestation of any other significant metabolic, hematologic, pulmonary, cardiovascular, gastrointestinal, neurologic, immune, hepatic, renal, urologic disorders, or cancer that, in opinion of the investigator, would make the candidate ineligible for the study
- History of stomach or intestinal surgery (except appendectomy) or major abdominal, thoracic or non-peripheral vascular surgery within one year prior to the randomization date
- Any disease or condition that seriously affects body weight and/or body composition

Laboratory Exclusion Criteria

- Potassium level above the upper limit of normal at the screening visit confirmed by a test repeated within two weeks
- Hemoglobin, hematocrit, RBC, or iron level below the lower limit of normal at the screening visit confirmed by a test repeated within two weeks
- Evidence of active liver disease or ALT levels above 1.5 times the upper limit of normal

Psychiatric and Behavioral Exclusion Criteria

- Individuals who practice a vegan dietary lifestyle
- History or clinical manifestation of any eating disorder as determined by IDED-IV when the ratings for each of the diagnostic criteria are rated as “3” or more
- History or clinical manifestation of any subclinical eating disorder as determined by IDED-IV when the ratings for each of the diagnostic criteria are rated “3” or more for 5 or the 8 combined symptoms for bulimia and anorexia nervosa.
- Any history of pharmacologic treatment for a psychiatric disorder within one year prior to the randomization date or a history of more than one episode of a pharmacologic treatment for a psychiatric disorder within lifetime
- History of drug or alcohol abuse (up to 14 drinks a week are allowed) within the past two years. Drug abuse is defined as any use of an illegal substance, including marijuana, at any time within the past two years.
- Individuals who present with a BDI score of ≥ 20 at screening or baseline

Medication Exclusion Criteria

- Short-term (less than a month) treatment with steroids within six months prior to the randomization date
- Treatment with steroids for more than a month within five years prior to the randomization date
- Regular use of other medications, except contraceptives (any form of contraception is allowed including hormone-releasing agents)

Other Exclusion Criteria

- Individuals who participated in the CALERIE Phase 1 studies
- Individuals who have lost a gained ≥ 3 kg over the past six months

- A volunteer must be either be a never-smoker of tobacco products or an ex-smoker who quit completely at least 12 months prior to the screening visit
- Individuals who donated blood within 30 days prior to the randomization date
- Concurrent participation in any other interventional study
- Individuals who smoke or have smoked in the past year
- Pregnant or breast-feeding women or women who are planning to become pregnant before the scheduled end of the intervention
- Individuals who were engaged in a regular program of physical fitness involving some kind of heavy physical activity (e.g., jogging, running or riding fast on a bicycle for 30 minutes or more) five or more times per week over the past year
- Unwilling to be assigned at random to the CR or control intervention
- Unwilling or unable to adhere to the rigors of the CR intervention over the entire two-year intervention period
- Individuals who unable or unwilling to discontinue dietary supplements or adhere to the alcohol consumption restrictions during the study
- Unwilling or unable to adhere to the rigors of the data collection and clinical evaluation schedule over the entire two-year period follow-up period

From earlier Design Committee's discussions, couples and family members that live together should be limited from enrolling in CALERIE.

If interested couples/family members present for screening, study staff should reinforce an earlier decision that only one member per household can actively participate in the CALERIE study. The Design Committee felt multiple members of households randomized to different treatment assignments, increased the likelihood of non-adherence to different diet and visit measures over time. If household members are interested in calorie restriction, they can be encouraged to follow this on their own, but not actively participate in the study. Only one member of the household, who is found eligible for the study, can be randomized and actively participate in the study's measurements.

5.3 Preliminary / Telephone Interviewing Preparations

The CALERIE phone screen form (Screening CRF pages 1-2) is needed to conduct a phone interview. Copies of this form and a BMI chart are kept by the phones. The screening process begins when a volunteer contacts a site by phone or email. Phone interviews are expected to take an average of 20 minutes. If study staff does not have the time to answer a CALERIE phone call or if a call comes outside regular business hours, the caller will be greeted by a message explaining that call volume is currently high and a staff member will contact them as soon as possible. The caller will be asked to leave their name, telephone and best hours to reach them. Return calls will be made promptly and in the order they were received.

5.3.1 Organizing the call list – (to be done at the start of the day)

- Check the voice mail for messages. (Calls need to be returned within 24 hours)
- Ask the Study Manager/staff for information on any other interested persons screened(e.g., personal referrals, calls taken by other staff members and email inquiries. Contact information for potential participants from any other source

should be put on the Call Log and a return phone call should be made to complete the phone screen).
- Complete the Call Log (The call log is located by the phone). Record information including: Phone number, Name, Time to call and if they have been contacted yet.
- Keep the call log updated as phone screens are completed and messages are retrieved from voicemail.

5.3.2 Preparing to make a phone call

All screening items are to be kept by the phone used to screen callers. Phone calls will come throughout the day and screeners need to be ready to take the calls. Please insure that you have the following items close to the phone and available to you:

- Call log
- Phone screen form
- Inclusion/exclusion criteria
- Study brochure
- Appointment calendar
- Caller's phone number (if returning the call)

5.3.3 Making return calls / receiving calls

- Answer incoming calls professionally. (Example: Applied Physiology Lab, this is Becky with the CALERIE study, may I help you?)
- Should the caller reach the voice mail system, the voice mail message should give the caller all necessary information needed to return the call. (Example: Hello, you have reached the CALERIE study being conducted in the Applied Physiology Lab at Washington University. We are unable to answer your call at this time. Call volume is very high. However, a staff member will contact you as soon as possible. Please leave your name, telephone number, and the best time to contact you and your call will be returned in the order it was received. Thank you for your interest in the CALERIE study.)
- Return calls only at the time indicated by the screenee. If no time is specified on the message, call between 9:00 am and 8:30 pm. Do not return calls after 9:00 pm.

5.3.4 Completing the phone screen

- Clearly represent yourself.
- Ask the potential participant whether it is a good time for him/her to discuss the study and complete a 20-minute phone screen.
- Briefly describe the study to the caller (about 3 minutes).
- Answer any questions the caller may have. Try to keep this as brief as possible. More details can be given during screening visit 1.
- Ask the caller if he/she is interested in continuing with the phone screen interview.
- If yes, ask for verbal consent to answer a few demographic and medical history questions.
- Review the phone screen form with the caller and complete all items. Make sure all questions are answered and match exactly to how the caller responded. Do

not assume any answers. Repeat yourself if necessary but make sure the phone screen form is complete.

- Review the completed phone screen form to determine eligibility. The study inclusion/exclusion criteria are located by the phone**.**
- Inform the caller if he/she is eligible for the study.
- If ineligible, explain why and thank the caller for their time. Be polite and tell them you are sorry their participation in this study did not work out. There is always a chance that the caller will be eligible for a future study, so thank them for their interest. Also ask the caller if they would be willing to mention the study to anyone they feel may be interested. They can pass our number on to them so we can do a phone screen.
- If ineligible, record on the form the reason for exclusion. Separate the phone screen forms for individuals that may be eligible at a future date and give them to the study manager. (Example – A caller who is interested but has travel conflicts or health issues that will keep them from participating in the study at the present time. This phone screen form should be kept separate and the call log needs to be updated. If the person feels that 3 months from now they would be able to handle the time commitment or will no longer have any health issues, a return call should be made to determine eligibility).
- If as the phone screener, you are unable to determine eligibility, do not proceed with excluding the participant or scheduling visit 1. If you do not feel comfortable making an inclusion/exclusion decision based on certain circumstances, tell the caller that you need to review the phone screen with the study physician and study manager to determine eligibility. Pass the phone screen form onto the study manager. If additional information is needed from the caller or if eligibility has been determined, the study coordinator calls the participant to discuss.
- If the caller is eligible following the phone screen, ask the caller whether he/she is willing to make an appointment for a clinic visit.

5.3.5 Scheduling screening visit 1

- Record the callers name and screening visit 1 date on the appointment calendar.
- Confirm the appointment date and time with the caller. The first visit should be a fasting visit, since a clinic weight will need to be obtained to confirm eligibility.
- Ask if the caller has access to the Internet.
- If yes, direct him/her to the CALERIE website. Also offer to mail a study brochure and directions to the site prior to visit 1.
- If no, ask the caller whether he/she wants to receive a study brochure and directions to the clinic by mail (Mailing may not be an option if the in-person visit is within the next few days.
- Provide caller with directions to the clinic, if mailing is not an option.
- Request that the interested candidate call back if he/she decides not to continue the screening process.
- If caller indicates that he/she needs more time to think about his/her participation, schedule a follow-up call. Record this information on the Call Log for a return phone call on that particular date and time.
- Thank the caller for their time and wish them a “pleasant day”. Remind them that they may call you at any time if they have further questions prior to visit 1.
- Following the call, complete the phone log.

5.3.6 Procedures to record call volume and assign return calls to staff

- After calls, review the call log for completeness.
- At the end of the day, provide the completed daily call log to the Study Manager.
- Study Manager completes the daily activity report which includes daily information of how many calls were received, how many calls were made, how many people completed phone screens, how many people were eligible following the phone screen and how many people were scheduled for screening visit 1.
- Provide daily activity report, phone screen forms and copy of the Call log and a copy of the appointment calendar to the Study Manger.
- Study Manager will review the daily activity report and call log to determine what calls need to be rescheduled for the following day.
- Study Manager assigns return call assignments to the phone screener for the following day.

5.4 Screening Visit 1

5.4.1 Organization prior to Visit 1

One day prior to the visit, a research assistant gathers the visit 1 forms together and makes a screening binder for the subject. A checklist for monitoring the visit is on the front of the binder.

5.4.2 Preparations for Screening Visit 1

The following materials and equipment are needed to conduct Screening Visit 1:

- IRB Approved Informed Consent
- Authorization for Release of Medical Records
- Authorization for Use and Disclosure of Protected Health Information for Research Purposes
- Screening 1 Checklist
- Stadiometer
- Weighing Scale (Digital)
- Study Video
- Study Brochure
- Demographic Questionnaire (Screening CRF page 5-6)
- General Dietary Questionnaire (Section 5 - Appendix B)
- Menus of the 27 days of feeding
- Inclusion/Exclusion Criteria Form
- Activity Assessment (Section 9.7.3)
- Lifestyle and Behavioral questionnaires
  - Eating Inventory (Section 9.10)
  - Multiaxial Assessment for Eating Disorder Symptoms (Section 9.10)
  - Structured Clinical Interview for Diagnosis of DSM-IV Personality Disorders (Section 9.10)
  - Beck Depression Inventory (Section 9.10)
- Body Acceptability Morph (This assessment may be preformed at SV1 or SV2, depending on site's resourcing)
- CALERIE ID Assignment Log

5.4.3 Conducting Screening Visit 1

The volunteer should be informed to come in fasting to the first visit. The order of these procedures and tests can vary, however the screening informed consent must be obtained prior to any study specific procedures being conducted. Please verify that screening visit 1 inclusion/exclusion criteria has been met prior to administration of study questionnaires. Since the order of the visit may vary, a checklist is being used to monitor completion of these procedures.

Study Coordinator

- Greet participant and bring them to a private room for the consent process.
- Explain to the participant what will happen at today's visit.
- Present the screening informed consent to the participant and review the consent in its entirety as described in Section 5.4.4.
- Address any questions and/or concerns the participant might have concerning the study or the screening process.
- Have the participant sign the informed consent. Witness the participant signing the consent form. Then sign the consent form to verify that study personnel administered the consent form and witnessed the participant signature.
- Document on a progress note that consent was obtained and all questions were addressed.
- For eligible participants, take them to a designated room to view the study video. If the participant has already seen the video, then proceed with remaining screening procedures.
- Once the participant has completed the study video, review the goals of the study, expectations of the study and volunteer requirements of the study.
- Again, address any questions and/or concerns about the study.
- If the participant has not yet received the study brochure, provide them with a copy and address any questions.
- Verify that the volunteer was fasting for at least 8 hours prior to obtaining the weight, if so; bring the participant to the exam room for weight and height measurements.
- Determine the participant's weight and height per the protocol outlined in MOP sections 9.3.1 and 9.3.2.
- Calculate the participant's BMI using the protocol outlined in MOP section 9.3.3.
- If the participant's BMI is in the study range and they have signed the informed consent, then assign a CALERIE ID using the protocol outlined in MOP section 5.4.6
- If the participant's BMI is not in study range, thank the participant for his/her time and tell them they are free to leave. If the BMI is slightly above the upper limit for the study (e.g., 28.1, 28.3, you may wish to invite the participant to come to the clinic in about 1 or 2 months for a repeated measurement.
- Provide psychological/QOL questionnaires to participants for completion. Review questionnaire instructions with the participant.
- For participant's eligible to complete screening visit 1, please provide a pen, pencil, hard writing surface and a quiet area to complete the screening psychological questionnaires. Please see the corresponding MOP sections for further explanation of how to complete and review the forms. A copy of all forms can be found in Section 9.10 and 9.11 of the MOP.

- Remain at reach for the participant in the event of questions or problems that arise while the participant is completing the questionnaires.
- When the participant informs you they are finished with the questionnaires, check all forms for completeness. If there are any mistakes or missing information, have the participant make the necessary changes or additions. Do not make any corrections on the forms completed by the participant!
- Capture menses cycle data for female participants for future reference.
- Call the study dietitian to the outpatient clinic.

Psychologist/Study Measurement Leader

- Have the participant complete the computerized Body Acceptability Morph as described in Section 9.10.3.1. Depending on site resourcing, this assessment may be performed at SV1 or SV2.

Study Dietitian

- Meet with the potential study participant to discuss major food allergies, supplement use or other dietary issues that may affect study participation.
- Review the General Dietary Questionnaire with the participant.
- Review the menus for the first 27 days of provided feedings
- Voice any concerns about the participant to the study coordinator or study manager.
- Notify the staff that the participant is ready to continue with the remainder of their visit.

Study Coordinator

- Review the participant's screening binder and confirm that the participant has completed all procedures for this visit.
- Verify that the participant is interested in continuing in the screening process.
- Schedule the participant for the next visit in 4-10 days.
- Instruct participant to fast (nothing to eat or drink except water) for at least 8 hours prior to the next visit.
- If any issues arise between screening visit 1 and the scheduled screening visit 2, contact the participant to clarify the information and take any required further action.

Research Assistant

- Fax any required documents to the coordinating center and complete any required CRF's for this visit
- Route the completed psychological questionnaires to the psychology department for review and scoring.

5.4.4 Informed Consent

The screening informed consent is separate from the study's main consent form. By signing the screening informed consent, the participant agrees to complete screening tests performed during the three screening visits.

5.4.5 Obtaining informed consent (at beginning of screening visit 1)

- Copies of the informed consent are on file in the office of the study coordinator.
- Study coordinator meets with the participant prior to starting screening visit 1. The informed consent **must** be signed prior to continuing any screening procedures or study activities with the participant.
- Review the document with the participant. The IRB requires that the participant read the informed consent prior to signing. Once the participant has read the document and agrees to sign, ask if he/she has any questions. Take as much time as necessary to review the document and to make sure the participant understands what they are signing.
- If the participant has no further questions, agrees that they understand the informed consent and is willing to move forward, have them sign and date the consent form.
- The study coordinator should witness the signing and must sign and date the form to verify.
- Make a copy of the signed informed consent to give to the participant.
- File the original informed consent in the patient folder.
- Remind the participant that even though they signed the informed consent they have the right to refuse any testing or drop out of the study at any time for any reason without consequence.

5.4.6 Assigning a CALERIE ID

Once a site has determined that a subject has signed the Screening Informed Consent Form and the BMI is verified, the site may refer to their site specific CALERIE ID Assignment Log (Appendix A), provided at study start-up and assign a CALERIE ID to the participant. The CALERIE IDs are listed numerically and should be assigned in chronological order. As subjects come in for screening visit 1, and are consented, the next available ID number on the log should be assigned. On the ID Assignment Log, the study coordinator should enter the subject's initials, date of birth, gender and date the ID was assigned. The ID number will never be assigned to another study participant. If this individual withdraws or is later found ineligible, the assigned ID number will be retired at that point in the study.

During monitoring visits, the study monitor will review each site's CALERIE ID log to verify that ID numbers are being assigned in a chronological order and never reassigned to another participant.

5.5 Screening Visit 2

5.5.1 Between Visits 1 and 2

At least two days prior to the visit, a Psychologist reviews the completed questionnaires from the first visit to determine what interviews are necessary during this visit. This is important because the visit time will vary by the number of interviews planned.

One day prior to the visit, a research assistant adds new visit 2 forms to the binder and checks for already completed forms. A checklist for monitoring the visit is added as a front page for the visit section.

One day prior to the visit, the Phlebotomist verifies that there are screening visit kits available for blood and urine sample collection and prepares labels.

5.5.2 Preparations for Screening Visit 2

The following materials and equipment are needed to conduct screening visit 2:

- Blood and Urine Collection Kits
- Calibrated BP manometer
- Calibrated ECG machine
- Screening visit 2 Checklist
- Completed Psychological Questionnaires and Body Acceptability Morph Information (If the Body Acceptability Morph was not performed in SV1, this must be completed in SV2)
- Medical History Form
- Medications Form
- Physical Exam Form
- 14-Day Food Diary
- 7-Day Calendar

5.5.3 Conducting Screening Visit 2

The order of these procedures and tests can vary however the fasting blood and urine samples must be obtained first and participant provided with a breakfast. . Since the order of the visit may vary, a checklist will be used to monitor completion of the visit procedures.

Study Coordinator

- Greet participant and verify s/he is fasting. Take participant and a binder to the Phlebotomist.
- If the participant is not fasting, reschedule the blood and urine collection for the next visit, mark the checklist to indicate rescheduling, and continue with other visit procedures.
- Answer any questions the participant might have.

Phlebotomist

- Set-up the screening visit kit ready with preprinted labels.
- Obtain clean catch urine and attach appropriate label to the vial.
- Draw blood samples for safety labs, process, and attach appropriate label for Labcorp. (Detailed sample preparation procedures are outlined in Section 12.0.) Samples that cannot be processed immediately are stored under recommended conditions until processed.
- Notify staff that the participant is ready to continue with other visit procedures.
- Complete paperwork for the laboratory and contact the lab regarding sample pick-up.
- Store samples under recommended conditions until they are picked-up by the lab.
- Document that samples were picked up.

Study Staff certified to take vital signs

- Obtain vital signs as outlined in Section 9.2.1 and record. This includes temperature, pulse, and BP. If the BP is found to be in the acceptable range, ≤140/90 mmHg, the visit continues. However, if the participant's blood pressure is found to exceed this limit, the participant is referred to their physician for follow up and excluded from the trial. (Note: If the subject does not have a known history of hypertension, the BP can be retried after letting the subject relax for at least five minutes. If the BP still exceeds these limits, the participant should be referred to their physician for follow-up.)
- Conduct an EKG as described in Section 9.12 and attach strip.
- Notify staff that the participant is ready to continue with the next part of their visit, which most likely would be the physical.
- Check to see if the participant has had breakfast.

Physician

- A complete medical history performed during screening will include a review of all major organ systems and all medications taken during 30 days prior to screening, as well as reproductive status, contraceptive and menstrual history for women, where appropriate. Use of an appropriate method of contraception will be verified at Month 1, 3, 6, 9, 12, 18 and 24 month visits. These forms are to be completed as described in Section 9.2.1. Copies of the forms can be found in Case Report Form Page 23 and 24.
- Review vital signs and EKG.
- Perform a physical examination to determine eligibility of the participant.
- Document results by signing the medical history and physical examination forms.
- Notify staff that the participant is ready to continue with their visit.

Psychologist

- If the Body Acceptability Morph was not given at SV1, then it should be given at SV2 prior to the interview measures.
- Complete the Barriers to Intervention Interview with the participant using the standardized questionnaire outlined in Section 5.0 Appendix C. This is a guided interview.

- Conduct any recommended interviews as needed; Structured Clinical Interview for Diagnosis of DSM-IV Personality Disorders (SCID II) and/or Personality Interview and Interview for Diagnosis of Eating Disorder (IDED-IV). These interviews are conducted as described in Section 9.10.
- Notify staff that the participant is ready to continue with their visit.

Dietitian

- Review the completed Dietary Screening Questionnaire found in Section 5.0 Appendix B.
- Instruct participants in how to complete a 14-day food record as outlined in Section 9.5.
- Notify staff that the participant is ready to continue with their visit.

Study Coordinator (this should be the final step)

- Review folder and confirm that the participant has completed all of the procedures for this visit.
- Schedule participant for the next visit for approximately 2 weeks (+/- 3 days).

5.6 Screening visit 3

5.6.1 Between Visits 2 and 3

Study Coordinator

- At least two days prior to the visit remind the participant to come in fasted if the blood draw is rescheduled for this visit from Screen visit 2 or if a repeat blood draw is requested by the study physician.
- Remind participant to bring the completed 14-day food record.
- Ensure that a checklist for monitoring this visit is added to the front of the binder.

5.6.2 Conducting Screening Visit 3

Study Coordinator

- Greet participant and verify that they have brought their food record.
- Verify that they are fasting (only for those participants for whom a fasting blood draw was not obtained at Screen visit 2 OR if a repeat blood draw was requested by the study physician).
- If a blood draw is scheduled take participant and his/her binder to the phlebotomist.
- After the blood draw is complete ensure that the participant is provided with breakfast before proceeding with other screen 3 activities.
- Answer any questions the participant might have (for participants who have a blood drawn do this after breakfast).
- Document that the participant's questions were addressed.
- Take participant and his/her binder and food records to the dietitian.

Study Dietitian

- Verify that the participant has accurately completed the14-day food diary that was given at screening visit 2.
- Ensure that the food record is performed as per given instructions.
- Review food record for general accuracy, compliance and motivation to adhere to study guidelines.
- If the food record is satisfactory after review, document this on the screening forms and place in binder for overall evaluation discussions.
- If the participant did not completely (12 out of 14 days at minimum) or accurately keep a 14-day diet record, ask him/her to repeat the food record for 7 days and schedule a follow up visit with the participant to review the record and inform study coordinator about this date.

Study Coordinator

- Inform participant that the site study team will review all screening results to determine final eligibility and that they should expect to be contacted within two weeks and notified about their status with regards to participation in the study.
- For those participants who are given a repeat food record or if blood work is performed for the first time at screen visit 3 – inform them that they will be contacted for additional follow-up.

Study Coordinator

- Review binder and confirm that the participant has completed all of the procedures for this visit.
- Ensure that all screening paper work including screening summary is in the binder for each participant.

5.6.3 Multidisciplinary Team Meeting

The Study Manager and Coordinator

- Ensure that the review team has all the relevant screening summaries and checklists as well as physician and behaviorist/psychologists notes.
- Participate in the team discussion.

Multidisciplinary team

- Decides that the participant has successfully completed all screening components and that the individual is both eligible and suitable for the study and that they are officially approved to participate in the study.
- Document on the screening checklist that screening has been completed and the participant has been deemed eligible by the multidisciplinary team. Place the screening checklist in the participant's binder.

5.6.4 Informing the Participant of Official Enrollment

The Study Coordinator

- Call the participant and congratulate / welcome them to the study.
- Inform them of their official acceptance to the study.
- Obtain suitable dates from the participant to begin the study.
- Inform the participant that an acceptance letter and finalized study schedule is being sent to them. Copy these documents and place them in the correspondence section of the participant's binder.

Appendix A

CALERIE Phase 2 ID Log Site = PBRC

CALERIE ID	Subject's initials	Date of birth	Gender (M/F)	Informed Consent date	Randomized? (√)	Date of randomization	Randomized Intervention (√)
01-0001		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0002		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0003		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0004		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0005		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0006		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0007		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0008		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0009		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0010		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0011		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0012		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0013		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0014		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0015		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0016		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0017		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0018		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0019		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0020		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0021		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0022		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0023		___/___/___		___/___/___		___/___/___	__ control __ CR

01-0024		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0025		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0026		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0027		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0028		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0029		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0030		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0031		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0032		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0033		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0034		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0035		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0036		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0037		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0038		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0039		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0040		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0041		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0042		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0043		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0044		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0045		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0046		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0047		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0048		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0049		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0050		___/___/___		___/___/___		___/___/___	__ control __ CR

01-0051		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0052		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0053		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0054		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0055		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0056		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0057		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0058		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0059		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0060		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0061		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0062		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0063		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0064		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0065		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0066		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0067		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0068		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0069		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0070		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0071		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0072		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0073		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0074		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0075		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0076		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0077		___/___/___		___/___/___		___/___/___	__ control __ CR

01-0078		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0079		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0080		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0081		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0082		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0083		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0084		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0085		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0086		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0087		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0088		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0089		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0090		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0091		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0092		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0093		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0094		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0095		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0096		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0097		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0098		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0099		___/___/___		___/___/___		___/___/___	__ control __ CR
01-0100		___/___/___		___/___/___		___/___/___	__ control __ CR

Appendix B

Name: _____ Date: _____

CALERIE DIETARY SCREENING QUESTIONNAIRE

1. There will be a lot of record keeping involved in this study; are you willing to complete a 14-day food record during screening, at several time points during the 2-year study, and daily food records if randomized to the intervention group? Yes _____ No _____

2. Do you have any food allergies? Yes _____ No _____

   If yes, please list your food allergies:

   _____
   _____
   _____
   _____
   _____

3. Do you have any food intolerances? Yes _____ No _____

   If yes, please list your food intolerances:

   _____
   _____
   _____
   _____
   _____

4. Please list any other food likes/dislikes that may influence your study participation:

   _____
   _____
   _____
   _____
   _____

5. Do you follow or are you required to follow any special diets or food restrictions (vegetarian, low carbohydrate, etc)? Yes _____ No _____

   If yes, please list all diet or food restrictions:

   _____
   _____
   _____
   _____
   _____

Screen Visit 1
(To be self-administered by volunteer and then reviewed by RD)

6. Are you currently taking any dietary supplements? Yes _____ No _____

If yes, please list the supplements:

_____
_____
_____
_____
_____

7. Are you willing to stop dietary supplements or any multivitamin and mineral supplements that you are currently consuming and take the multivitamin and mineral supplement provided by our Center? Yes _____ No _____

8. Have you had any problems with food or with eating? Yes _____ No _____

If yes, what are they?

_____
_____
_____

9. How many meals each week on average do you eat out at restaurants or from take-out?

_____
_____
_____

10. How many meals and snacks do you eat each day and in what location(s) are these normally eaten?

Number of meals: _____ Number of snacks: _____

Location of meals and snacks:

_____
_____
_____

11. Do you cook? Yes _____ No _____

12. Who usually does the cooking in your household?

_____
_____

13. Who usually does the grocery shopping in your household?

_____
_____

Screen Visit 1

14. Do you use frozen foods (such as frozen entrees) regularly? Yes _____ No _____

    If yes, please list some common frozen foods you use:
    _____
    _____
    _____

15. Do you use meal replacements such as bars or liquid shakes? Yes _____ No _____

    If yes, please list some common meal replacements you use:
    _____
    _____
    _____

16. Are there any foods that you tend to overeat? Yes _____ No _____

    If yes, please list these foods:
    _____
    _____
    _____

17. What beverages do you usually drink? How much of these beverages do you usually consume in a day?
    _____
    _____
    _____

18. What was your heaviest weight and lightest weight as an adult?

    Heaviest = _____ Lightest = _____

19. What were the reasons or circumstances leading up to your heaviest and lightest weights?
    _____
    _____
    _____

20. In the event you are randomized to the calorie-restricted group:

    Are you willing/able to eat only the items provided by our Center for a 4 week period? Yes____ No____

Notes (for RD use only):
_____
_____
_____
_____

Barriers to Effective Intervention
Semi- Structured Interview

Date: _____
Participant ID#: _____
Primary Interviewer: _____ Additional Rater: _____

<u>Note to Interviewer</u>: Please see page 12 of this interview for a checklist of potential concerns related to an individual's candidacy for the CALERIE study. Please be aware of these concerns as you interview potential participants for the CALERIE study.

1. **Understanding and Reasons For Joining:**

Please explain your understanding of the purpose of the CALERIE study.

_____
_____
_____

Please describe your understanding of the two conditions (CR and Regular diet groups). (**Correct misconceptions; Ensure participant understands how groups differ**).

_____
_____
_____

Tell me your most important reason for wanting to be in this study. Other reasons?

_____
_____
_____

Interviewer rating of participant's capacity to understand the CALERIE trial : _____ / 5

_____	_____	_____	_____	_____
1	**2**	**3**	**4**	**5**
Poor understanding	does not understand key aspects	understands most aspects	generally understands	completely understands

Other comments/questions from participant relative to their candidacy:

_____
_____
_____

2. Willingness to accept random assignment.

Are you willing to be assigned to either of the groups or do you have such a strong preference for being in only one that you are unwilling to be randomized? Do you understand the 2:1 randomization for this study? (**Ensure participant understands random assignment and is okay with being assigned to either condition**)

_____
_____
_____

Are you okay with being assigned to the Regular diet group? Do you mind going through the same assessments as those in the CR group, but being asked not to alter your current eating habits?

_____
_____
_____

Interviewer rating of understanding of the treatment assignment process: _____ / 5

_____	_____	_____	_____	_____
1	**2**	**3**	**4**	**5**
Will not accept random assignment	Prefers one group and hesitant to accept random assignment	Prefers one group but will accept random assignment	Generally ok with random assignment	Completely ok with random assignment

Other comments/questions from participant relative to their candidacy:

_____
_____
_____
_____

3. Willingness to Modify Diet:

Are you interested in and willing to eat less food and fewer calories over a two-year time period? This means that you will engage in calorie restriction.

Are you willing to modify your typical diet in order to achieve calorie restriction during this two-year study? These modifications could include restricting the number of times that you eat out, or changing the types of foods that you select when you eat out. It could also include changing the types of foods that you eat when you prepare your own meals.

Are you the person who prepares meals for your household? If so, are you willing to consider the possibility that you might have to change the way in which you prepare your meals in order to achieve calorie restriction? This might include eating smaller portions compared to the rest of your family, or preparing and eating different dishes or meals.
If you are not the person who prepares meals in the household, is the person who prepares the meals willing to support your efforts to achieve and maintain calorie restriction? Is this person willing to be flexible in the types and amounts of foods that are prepared for your meals?

Are you willing to record your food intake in a pen-and-paper food diary during assessment periods and a Personal Digital Assistant on a daily basis over the course of the rest of the study? Can you foresee anything getting in the way of your ability to do this?

Interviewer rating of willingness to comply with dietary requirements: _____ ***/ 5***

_____	_____	_____	_____	_____
1	**2**	**3**	**4**	**5**
None, answers no to any question	**Marginal,** hesitant to say yes to <u>three</u> or more questions	**Partial,** hesitant to say yes to <u>two</u> of the four questions	**Good,** hesitant to say yes to only <u>one</u> of four questions	**Excellent,** confident can comply with requirements

Other comments/questions from participant relative to their candidacy:

4. Ability to adhere to study schedule/demands:

Please describe your understanding of the daily time commitment required to be in the CALERIE study? (**Ensure participant understands daily time requirements:** food recording, etc.). ***Ask them to repeat back to you. "Just so I'm sure you understand what's involved, can you please repeat back to me your understanding of the daily time requirements."***

_____

_____

_____

How far do you live from our center? How far do you work from our center? Do you see any work or family commitments that might interfere with your ability to participate in the study? Given your current schedule, do you feel you would be able to handle the daily time demands of this study?

_____

_____

_____

Please describe your understanding of the group and individual meeting schedule in the CALERIE study? (**Ensure participant understands meeting schedule**). ***Ask them to repeat back to you.***

_____

_____

_____

What obstacles might interfere with your ability to make the group sessions (e.g., transportation, work schedule, child-care, family obligations, etc)?

_____

_____

_____

Do you believe that attending group and individual sessions are necessary to help change eating habits and problems that might interfere with optimal performance in the study?

_____

_____

_____

What resources do you have available to you that you could use to problem-solve any of these challenges should they occur during the study?

_____

_____

Tailor this question to match the circumstances at your site: Do you foresee difficulty attending four weeks of infeeding? During infeeding, you will report to the center up to two times per day to eat meals, and your lunch and weekend meals will be packed for take-out. Alternatively, you could receive pre-packaged food from the center, and all of your meals and snacks would consist of this food.

_____

_____

_____

Can you see any potential reasons why you might be dissatisfied with the study as it has been described?

_____

_____

_____

Interviewer rating of participant's ability to adhere to study demands: _____ / 5

_____	_____	_____	_____	_____
1	**2**	**3**	**4**	**5**
(>4 obstacles) (no resources) Poor understanding	(4 obstacles) (≤ 1 resources) does not understand key aspects	(3 obstacles) (≥ 1 resources) understands most aspects	(2 obstacles) (≥ 1 resources) generally understands daily requirements	(≤ 1 obstacle) (≥ 1 resources) completely understands daily requirements

5. Previous attempts at weight loss or exercise programs:

Have you participated in any weight loss programs, health or social support groups, or have you lost a significant amount of weight on your own during the past year? Past ten years? Lifetime? What was your largest weight loss? What methods did you use? If no, go to #6.

_____
_____
_____
_____

If yes, how long did you maintain your largest weight loss? Other weight losses? How much did the counseling process (or having a counselor) contribute to your success?

_____
_____
_____

Which parts of these programs did you feel were ***successful*** for you?

_____
_____
_____

Which parts of these programs did you feel were ***unsuccessful*** for you? Were there other parts about the program that you did not like?

_____
_____
_____

Interviewer rating of participant's past weight loss attempts: _____ / 5
(e.g., small = less than 10 lbs, average = 10 – 20 lbs, large = 20 lbs or more)

_____	_____	_____	_____	_____
1	**2**	**3**	**4**	**5**
<5 lb weight loss not sustained	5 to 10 lb weight loss sustained for over six months	>10 lb weight loss sustained for less than six months (No previous weight loss attempts)	>10 to 20 lb weight loss sustained for over six months	> 20 lb weight loss sustained over six months

6. Acceptability of losing weight in the study:

Have you ever lost so much weight that you or others felt you were "too skinny?" How comfortable would you be with losing 15% (**give participant approximate # in pounds**) of your body weight? Are you willing to remain in the program and continue to lose weight or maintain your weight loss, even though family and friends might pressure you to gain weight?

_____
_____
_____

Interviewer rating of participant's acceptability of potential weight loss: _____ / 5

1	2	3	4	5
Not Acceptable (would likely drop out of study)	**Marginal** (would potentially drop out of study)	**Neutral** (unsure what effect would occur)	**Acceptable** Would likely remain in study even if receiving resistance for weight loss	**Very Acceptable** Would remain in study even if receiving resistance for weight loss

7. Current weight loss activities:

Describe any weight control activities you are currently engaging in? How long has it been since you have been on a weight loss regimen?

_____
_____
_____

What is your current eating pattern? Would following the CALERIE restriction plan be very difficult for you?

_____
_____
_____

Please describe your current exercise pattern (days per week, activity, intensity, duration)?

_____
_____
_____

Have you ever exercised ***regularly*** in the past and then stopped? How long ago? What happened?

_____
_____
_____

Interviewer rating of current diet and exercise behaviors: _____ / 5
(PA = Physical Activity and/or structured exercise)

_____	_____	_____	_____	_____
1	**2**	**3**	**4**	**5**
Currently following weight loss regimen; PA > 5 day/wk	Stopped weight loss regimen in past month; PA ≥ 5 days/wk	Stopped weight loss regimen over one month ago; PA = 3 - 4 days/wk	Stopped weight loss regimen over three months ago; PA ≤ 3 days/wk	Stopped weight loss regimen over six months ago; PA < 3 days/wk

8. Support Systems:

How does your family (or close friends) feel about you participating in CALERIE? Would your family members be willing to eat the same foods as you while you are involved in this study? Have friends or family members ever pressured you to gain weight following a weight loss because they thought you looked too thin?

_____
_____
_____

What role do you play in the care of your family members? Would other family members be able to share the responsibility if a family member became sick?

_____
_____
_____

Do you feel comfortable in social situations and/or participating in a support group? Would these meetings interfere with your current work schedule? If so, how might you be able to resolve this conflict?

_____
_____
_____

How would you describe your communication skills? With individuals? In a group?

_____
_____

Considering your personal schedule for the next two years (work, family events, vacation/travel, holidays, weather driving, etc), is this a good time for you to begin a time-consuming study?

_____
_____

What type of transportation would you use to get to the clinic (site)? Are there any situations in which this transportation would not be available?

_____
_____

Would your work schedule allow you to come in for extensive assessments (e.g., 2 day inpatient stays)? Have you discussed this situation with your supervisor or colleagues? How long have you worked at your present job? Do you have any plans of leaving in the next 6 months? two years?

_____
_____

Interviewer rating of participant's social support: _____ / 5

_____	_____	_____	_____	_____
1	**2**	**3**	**4**	**5**
(unmanageable (schedule (no support) (social support)	(very busy schedule) (some social difficulties) (minimal help with caretaking) (little support)	(busy schedule) (minor social difficulties) (some help with caretaking) (some support)	(manageable schedule) (no social difficulties) (lots of help with caretaking) (supportive family)	(good schedule) (not sole caretaker) (supportive family)

9. Adequacy of Behavior Run-In.

Have you experienced any difficulties making the screening appointments to date?

_____
_____
_____

Have you encountered significant scheduling difficulty for the screening visits?

_____
_____
_____

Interviewer rating of adequacy of behavioral run-in: _____ / 5
(e.g., 5 /7 days criterion, thoroughness, missing data). ***Need to extend/repeat***?

_____	_____	_____	_____	_____
1	**2**	**3**	**4**	**5**
Poor	**Partial**	**Marginal**	**Good**	**Outstanding**
failed to make screening appts.	some scheduling problems (at least 2 no show)	minor scheduling problems (at least, 1 no show)	minor scheduling problems (0 no shows)	no scheduling problems

Other comments/questions from participant relative to their candidacy:

_____
_____
_____
_____

Scoring Instructions – CALERIE Assessment of Barriers to Effective Treatment

A total score is computed for this assessment by summing the scores for each of the eight sections. This score represents the overall rating of the participant's suitability for this study.

1. Understanding and Reasons for Joining: _____ / 5
2. Willingness to accept random assignment and medical testing: _____ / 5
3. Willingness to comply with dietary requirements: _____ / 5
4. Ability to adhere to study demands: _____ / 5
5. Past weight loss attempts: _____ / 5
6. Acceptability of weight loss: ____/5
7. Current weight loss behaviors: _____ / 5
8. Support system; Readiness: _____ / 5
9. Adequacy of behavioral run-in: _____ / 5

Total Score = ___ / 45

Primary Interviewer _____ Date of administration _____

Secondary Rater _____ Date of administration _____

Recommendation based on this interview (this recommendation does not necessarily reflect the final recommendation, which takes into consideration questionnaire scores and performance on food intake monitoring):
(circle one)

Accept Do Not Accept Requires further eval. at screening 3

Barriers to Effective Intervention
Semi-Structured Interview: Mental Health

A: CALERIE Related Concerns & Notes: Checklist (Circle Yes or No for each)

1. Yes / No Noted participant desiring to lose weight for appearance reasons
2. Yes / No Noted participant desiring to be in the study for appearance reasons or desiring rigid control over eating
3. Yes / No Noted participant possessing a strong desire to engage in calorie restriction, particularly for appearance reasons or rigid weight control
4. Yes / No Noted participant admitting to not eating in restaurants already due to food phobias or rigid eating patterns, or that this adjustment would be easy
5. Yes / No Noted participant stating that they already eat smaller portions than the rest of their family at mealtimes
6. Yes / No Noted participant stating that they already monitor their food intake in a rigid fashion.
7. Yes / No Noted participant resisting this part of the study for fear of not preparing the food themselves, or concern over what might be in the food
8. Yes / No Noted participant engaging in dietary restriction or "extreme" dieting behaviors in the past or present in order to achieve weight loss and/or appearance improvement
9. Yes / No Noted participant utilizing eating disordered methods to lose weight in past or present, e.g. fasting, restrictive eating, purging, laxatives, diuretics, exercise, etc.
10. Yes / No Noted participant indicating that counseling was not effective
11. Yes / No Noted participant defining success by low weight levels, certain unhealthy appearances, or maintaining extreme dietary and/or exercise practices
12. Yes / No Noted participant experiencing medical concerns associated with eating disorders, e.g. dental problems, heart problems, edema, gastrointestinal problems
13. Yes / No Noted participant thinking that others felt he or she was too thin, wanting to return to that state, or wanting others to think that, even if they never reached that state. Note excitement about being exceptionally thin and why
14. Yes / No Noted any reports by participant that he/she was engaging in extreme dieting and/or exercise behavior
15. Yes / No Noted participant expressing discomfort in social situations

Extra notes related to items mentioned above:

B: Current Status of Body Image and Potential Eating Issues

1. Do you have any current concerns regarding your eating and your weight?

2. Do you currently go periods of time without eating (starvation) to control your weight? (If yes, describe.)

3. Do you think or worry a lot about your weight and body size? (Describe.)
Interviewer note: Note if this person is responding to this question in a way that pertains to obesity or an overestimation or dissatisfaction related to a thin body size.

4. Do you ever feel fat? (If yes, ask when do you feel fat?)
Interviewer note: Note if this person is responding to this question in a way that pertains to obesity or an overestimation or dissatisfaction related to a thin body size.

5. Do you ever feel too thin? (If yes, ask why/when)

6. How often does your body size affect the way you feel about yourself?
Interviewer note: Note if this person is responding to this question in a way that pertains to obesity or an overestimation or dissatisfaction related to a thin body size.

7. Do you ever binge (rapidly consume a large amount of food in a discrete period of time)?

8. When do your binge eating episodes occur?(during meals, after meals, throughout day, etc.)

9. How long does each binge usually last?

10. How often do you feel out of control of your eating during a binge?

11. Do you ever feel as though you have overeaten when you eat small portions of certain fattening foods? (Describe.)

12. How often do you eat large amounts of food when you don't really feel hungry? (Describe.)

13. How often do you eat and/or binge alone, or in secret? Why? (Check for embarrassment.)

14. Do you purge after meals or after a binge (vomit, abuse laxatives or diuretics)? If yes, how often?

15. Do you engage in vigorous exercise to control your weight? (intense exercise which is compulsive or obligatory from person's description aimed at ridding body of food/calories.)(If yes, ask what type and how often.)

C: Current Status of Psychopathology

1. History of psychopathology: Have you or your family members ever been diagnosed with any psychological disorders including but not limited to depression, anxiety disorders (including social phobia), eating disorders, bipolar disorder, etc.)

_____
_____
_____

2. Psychotic:
    a. Has it ever seemed like people were talking about you or taking special notice of you?
    b. Have you ever heard things others couldn't hear?
    c. Have you ever seen things others couldn't see?
    d. Did you ever feel like something was controlling your actions against your will?

_____
_____
_____

3. Depression: In the past month, have you felt down, most of the day nearly every day? If yes, describe.

    a. Have you ever felt worthless? If yes, describe.
    b. Do you often feel as though current activities are not as enjoyable as they once were?
    c. Have you ever considered ending your life?

_____
_____
_____

4. Mania: In your lifetime, has there been a period of time when you were feeling so good or hyper that other people thought you were not your normal self, or you were so hyper you got into trouble? If yes, describe. (Or a period of time so irritable started fights or arguments).

_____
_____
_____

5. Substance Use: Was there ever a period of time in your life where you drank too much or utilized drugs too much? If yes, describe.

_____
_____
_____

6. Anxiety Disorders:

    a. Panic: Have you ever had a panic attack, when you suddenly felt frightened, anxious, or extremely uncomfortable? If yes, please describe.

    _____
    _____
    _____

b. Social Phobia: Is there anything that you were ever afraid to do or felt uncomfortable doing in front of other people, like speaking, eating, or writing? If yes, please describe.
   1. Have you ever taken medication to reduce anxiety?
   2. Do you currently experience any of the following symptoms tremors, jitters, racing heart, or general discomfort) when talking in front of a group of people?
   3. Have you ever avoided social situations in which you may be evaluated? If so, do you currently do this?

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_____

c. Simple Phobia: Are there any things that you are especially afraid of, like heights, blood, closed spaces?

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_____

d. Obsessive-Compulsive Disorder: Have you ever been bothered by thoughts that didn't make any sense and kept coming back even when you tried not to have them? Please describe.
   i. Was there ever anything that you had to do over and over again and couldn't resist doing like washing your hands again and again, or checking something several times to make sure it was done right?

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_____

e. GAD: In the last six months, have you been particularly nervous or anxious or worry a lot most of the time? For example, do you worry most of the time and everyone you know thinks its excessive?

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f. PTSD: Have you ever had something happen to you that was extremely upsetting, e.g. a life threatening situation, a family death, or just hearing about something horrible?
   i. Have you ever experienced flashbacks, nightmares, or thoughts you can't get rid of? Please describe.
   ii. Have you ever felt as though you keep "re-experiencing" the event or avoiding doing things or thinking of things that may remind you of the event because it is so disturbing to you? Please describe.

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_____

g. Somatization: Do you worry a lot about your health? Does your doctor think you worry too much.

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