Complete Research Protocol (HRP-503)

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Template Instructions

Sections that do not apply:

- *In several sections, the addition of checkboxes for **Not Applicable** have been added to the template as responses.*
    - *If an N/A checkbox is present, select the appropriate justification from the list.*
    - *If an N/A checkbox is not present, or if none of the existing checkboxes apply to your study, you must write in your own justification.*
- *In addition:*
    - *For research where the only study procedures are records/chart review: Sections 6, 21, 22, 24, 25, 26 and 27 do not apply.*
    - *For exempt research: Section 6 may not apply. Section 6.1 will still apply if there is a study intervention.*

Studies with multiple participant groups:

- *If this study involves multiple participant groups (e.g. parents and children), provide information in applicable sections for each participant group. Clearly label responses when they differ. For example:*

Response Example
Intervention Group:
Control Group:

Formatting:

- *Do not remove template instructions or section headings when they do not apply to your study.*

If you are pasting information from other documents using the "Merge Formatting" Paste option will maintain the formatting of the response boxes.

Amendments:

- *When making modifications or revisions to this and other documents, use the **Track Changes** function in Microsoft Word.*
- *Update the version date or number **on Page 3.***

PROTOCOL TITLE:

Include the full protocol title.

Response: Weight management program for patients with first episode psychosis.

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response: Daniel Antonius

Department of Psychiatry

Phone(716) 898-5940
Email: danielan@buffalo.edu

VERSION NUMBER/DATE:

Include the version number and date of this protocol.

Response: 1 8-13-2021

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?

FUNDING:

Indicate any funding for this proposal. This should match the Funding Sources page in Click IRB.

Response: Department of Psychiatry

GRANT APPLICABILITY:

Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.

NOTE: This question does not apply to studies funded by a sponsor contract.

Include a copy of the grant proposal with your submission.

Response: Not funded by a grant, Under consideration for CTSI funding

RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response:

Location:Room 1152, ECMC

Address:462 Grider Street, Buffalo, 14215

Department: Psychiatry

1.0 Study Summary

Study Title	Weight management program for patients with first episode psychosis.
Study Design	This is a multiple baseline N of 1 intervention with 12 individuals
Primary Objective	Determine the feasibility, acceptability, and effect of a weight management program for patients prescribed antipsychotic medications for a first episode of psychosis.
Secondary Objective(s)	
Research Intervention(s)/ Investigational Agent(s)	Three month weight management program
IND/IDE #	
Study Population	Adults and adolescents participating in treatment through the NAVIGATE program for an initial episode of psychosis and one of their parents or a household family member (e.g., parent, guardian, grandparent, aunt or uncle).
Sample Size	12 patients and 12 family members
Study Duration for individual participants	Up to 9 months

Study Specific Abbreviations/ Definitions	Severe mental illness (SMI)

2.0 Objectives*

2.1 Describe the purpose, specific aims, or objectives of this research.

Response: This pilot study will determine the acceptability and potential value of a family–oriented weight management program for individuals receiving anti-psychotic medication for a first episode of psychosis.

2.2 State the hypotheses to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

Response: Patients will lose weight after treatment is initiated in comparison to the two month baseline during which they simply weigh themselves daily.

3.0 Scientific Endpoints*

3.1 Describe the scientific endpoint(s), the main result or occurrence under study.

NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should ***not*** *be a date.*

Response: The primary endpoint will be the participants' weights. Secondary endpoints will be participation in the weekly interventions and the percent of daily weight reports.

4.0 Background*

4.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.

Response: *Severe mental illness (SMI), such as schizophrenia and bipolar disorder, are associated with increased morbidity and mortality from somatic disorders. People with a severe mental illness have a life expectancy as much as 10-20 years less than people without such disorders (Lomholt, et al, 2019). These differences in morbidity are reflected in healthcare costs, with SMI patients incurring nearly $5,000 in annual Medicare costs for physical conditions more than patients without*

SMI with excesses observed for diabetes as well as ischemia and congestive heart failure. (Figueroa, et al 2020).

While there are a number of factors that contribute to the physical health risks of people with SMI, obesity is of particular importance. Obesity creates an increased risk for many common medical conditions, such as diabetes, heart disease, hypertension and cancer. Moreover, people with SMI are about twice as likely as those without to be obese (McElroy, 2009). While there has been some evidence that suggests that individuals with SMI may be predisposed toward obesity and metabolic dysfunctions, it is also clear that psychosocial factors and antipsychotic medications have a very strong impact.

Among the psychosocial factors that appear to play a role are low self-efficacy and motivation for physical/social activities, effects that may be exacerbated with the stigma experienced from the disorder, as well as from the effects of medications to treat SMI (Gates, Killackey, Philips, & Alvarez-Jimenez, 2015).

Antipsychotic medications also are powerful contributors to weight gain. D'Aurignac, Leonard, and Dubovsky (2014) demonstrated that olanzapine, but not a placebo, led to a significant weight gain of 3.74 lbs. among healthy participants in only two weeks. Moreover, while not all subjects who received olanzapine gained weight, subjects who gained weight on olanzapine gained an average of 5.28 lbs., and also experienced increases in LDL cholesterol, insulin, and leptin. Among adults with a first-episode psychosis, olanzapine resulted in an increase of 10.34 lbs. in 12 weeks, and increases in insulin, c-peptides and triglycerides (Graham et al, 2005). This increase in weight, as well as increases in cholesterol, leptin, and insulin, continue to increase over the first year of antipsychotics, and then stabilize (Mustafa, et al, 2019; Perez-Iglesias et al, 2014).

There have been numerous studies that have examined weight loss interventions among those with SMI. One of the most well-known, ACHIEVE, compared an 18 month lifestyle intervention (diet and exercise) with a control condition for SMI patients attending day treatment centers. At the end of the 18 months, patients who received the lifestyle intervention had lost 7.5 lbs., in contrast to less than .50 lbs. in the control. Aside from this lengthy and intensive intervention, most studies have not demonstrated this large of an effect. A recent meta-analysis examined 41 randomized clinical trials focusing on interventions that attempted to decrease body weight through improved diet, increased activity, or both (Speyer, et al, 2019). The overall conclusion was that

these interventions led to statistically significant weight loss that was of no clinical significance (a difference of approximately 4.8 lbs), and which did not persist beyond the intervention. While neither this meta-analysis nor an earlier one (Alvarez-Jimenez, Hetrick, Gonzalez-Blanch, Gleeson, & McGorry, 2008) found that the effects were stronger for patients with a shorter duration of disorder, studies of weight management in other samples often find that it is easier to prevent weight gain than to lose weight, given metabolic changes that occur with increased weight. As a result, there has been recent interest in interventions to prevent weight gain among patients experiencing their first episode of SMI.

While there has been interest in developing effective early interventions for patients experiencing their first episode of a SMI, most of the work has attempted to establish the acceptability and feasibility of interventions (e.g. Thompson, et al, 2020), or has conducted small, uncontrolled studies of changes in weight in a group receiving the intervention. There have been very few randomized clinical trials. For example, Curtis et al (2016) provided 26 patients with a 12 week lifestyle and life skills intervention and 23 patients with standard care. Only 57% completed the programs and were available for analyses. At the end of the 12 weeks, the intervention group, which contained three times as many women as standard care, only gained 4.0 lbs, while the standard care group gained 17 lbs. The largest and most well-controlled study to date was conducted by Alvarez-Jimenez and colleagues (Alvarez-Jimenez et al, 2006; Alvarez-Jimenez et al, 2010). This study randomized 28 patients to a 7-16 session early behavioral treatment including psychoeducation, dietary counseling, exercise, and behavioral therapy and 33 patients to routine care. Patients in the behavioral treatment had gained significantly less weight, 9.0 lbs, by the end of the 3 month program than patients in routine care gain, 15.2 lbs. Nearly 97% of the sample was successfully followed up one year later, and there were not differences in their weight.

Given the poor adherence in one study and the lack of a lasting effect, modifications of these weight management programs would be important to consider. One particular aspect that has been shown to be effective with adolescents is the involvement of a parent.

4.2 Include complete citations or references.

Response: *Alvarez-Jimenez, M., Gonzalez-Blanch, C., Vazquez-Barquero, J.L., Perez-Iglesias, R., Martinez-Garcia, O., Perez-Pardal, T., Ramirez-Bonilla, M.L., & Crespo-Facorro, B. (2006). Attenuation of antipsychotic-induced weight gain with early behavioral intervention in drug-naive first-*

episode psychosis patients: A randomized controlled trial. Journal of Clinical Psychiatry, 67(8), 1253-1260.

Alvarez-Jimenez, M., Hetrick, S.E., Gonzalez-Blanch, C., Gleeson, J.F., & McGorry, P.D. (2008). Non-pharmacological management of anti psychotic-induced weight gain: Systematic review and meta-analysis of randomised controlled trials. British Journal of Psychiatry, 193(2), 101-107.

Alvarez-Jimenez, M., Martinez-Garcia, O., Perez-Iglesias, R., Ramirez, M.L., Vazquez-Barquero, J.L., & Crespo-Facorro, B. (2010). Prevention of antipsychotic-induced weight gain with early behavioural intervention in first-episode psychosis: 2-year results of a randomized controlled trial. Schizophrenia Research, 116(1), 16-19.

Curtis, J., Watkins, A., Rosenbaum, S., Teasdale, S., Kalucy, M., Samaras, K., & Ward, P.B. (2016). Evaluating an individualized lifestyle and life skills intervention to prevent antipsychotic-induced weight gain in first-episode psychosis. Early Intervention in Psychiatry, 10(3), 267-276.

Daurignac, E., Leonard, K.E., & Dubovsky, S.L. (2015). Increased lean body mass as an early indicator of olanzapine-induced weight gain in healthy men. International Clinical Psychopharmacology, 30(1), 23-28.

Figueroa, J.F., Phelan, J., Orav, E.J., Patel, V., & Jha, A.K. (2020). Association of mental health disorders with health care spending in the Medicare population. JAMA Network Open, 3(3), e201210.

Gates, J., Killackey, E., Phillips, L., & Alvarez-Jimenez, M. (2015). Mental health starts with physical health: Current status and future directions of non-pharmacological interventions to improve physical health in first-episode psychosis. Lancet Psychiatry, 2(8), 726-742.

Graham, K.A., Perkins, D.O., Edwards, L.J., Barrier, R.C., Lieberman, J.A., & Harp, J.B. (2005). Effect of olanzapine on body composition and energy expenditure in adults with first-episode psychosis. American Journal of Psychiatry, 162(1), 118-123.

Hubbard, G., Thompson, C.W., Locke, R., Jenkins, D., Munoz, S.A., Van Woerden, H., Maxwell, M., Yang, Y.L., & Gorely, T. (2020). Co-

productions of "nature walks for wellbeing" public health intervention for people with severe mental illness: Use of theory and practical know-how. BMC Public Health, 20(1), 428.

Lomholt, L.H., Andersen, D.V., Sejrsgaard-Jacobsen, C., Ozdemir, C.M., Graff, C., Schjerning, O., Jensen, S.E., Straszek, S.P.V., Licht, R.W., Grontved, S., & Nielsen, R.E. (2019). Mortality rate trends in patients diagnosed with schizophrenia or bipolar disorder: A nationwide study with 20 years of follow-up. International Journal of Bipolar Disorders, 7(1), 6.

McElroy, S.L. (2009). Obesity in patients with severe mental illness: Overview and management. Journal of Clinical Psychiatry, 70, Supp. 3, 12-21.

Mustafa, S., Bougie, J., Miguelez, M., Clerzius, G., Rampakakis, E., Proulx, J., & Malla, A. (2019). Real-life assessment of aripiprazole monthly (Abilify Maintena) in schizophrenia: A Canadian naturalistic non-interventional prospective cohort study. BMC Psychiatry, 19, 114.

Perez-Iglesias, R., de la Foz, V.O.G., Garcia, O.M., Amado, J.A., Garcia-Unzueta, M.T., Ayesa-Arriola, R., Suarez-Pinilla, P., Tabares-Seisdedos, R., & Crespo-Facorro, B. (2014). Comparison of metabolic effects of aripiprazole, quetiapine and ziprasidone after 12 weeks of treatment in first treated episode of psychosis. Schizophrenia Research, 159(1), 90-94.

Speyer, H., Jakobsen, A.S., Westergaard, C., Norgaard, H.C.B., Pisinger, C., Krogh, J., Hjorthoj, C., Nordentoft, M., Gluud, C., Correll, C.U., & Jorgensen, K. (2019). Lifestyle interventions for weight management in people with serious mental illness: A systematic review with meta-analysis, trial sequential analysis, and meta-regression analysis exploring the mediators and moderators of treatment effects. Psychotherapy and Psychosomatics, 88(6), 350-362.

5.0 Study Design*

5.1 Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).

Response: This is a multiple baseline N of 1 design. Participants will chart their weight for two months prior to the initiation of a weight management program, and continue to chart their weight throughout the 3 month intervention and for 2 months following the intervention.

6.0 Study Intervention/Investigational Agent

6.1 Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.

Response: Families will receive a 12-week FBT adapted for first episode psychosis. This will be delivered in 12 weekly meetings with a trained case manager and two "eating plan" education sessions. Both the patient with psychosis and parents are targeted for eating and activity/exercise change to ensure a change in the shared family environment, which will also help weight control in both sets of participants, as well as medical issues that accompany obesity, including glycemic control, hypertension and hyperlipidemia. If parents are not overweight/obese, they will still target improved health behaviors. They will learn about GREEN, YELLOW, and RED foods (healthy vs. unhealthy foods), energy density, glycemic index of foods, reducing serving sizes, eating less, healthy lifestyle and programmed activity programs and recording their diets and activity. Weekly sessions will involve discussion of weight loss principles presented in modules in the weight control manual, and coaching parents and patients how to implement the Traffic Light Eating Plan and healthy lifestyle techniques. At each session, participants meet with staff and attend a brief problem solving session with their case manager where they will troubleshoot any expected or encountered issues with implementing the program. This intervention may be through Zoom (which is still approved for telemedicine interventions in New York) or in-person. The NAVIGATE program has used telemedicine with this patient group throughout the past year successfully. As part of treatment, participants will weigh themselves daily with a Bluetooth scale. Contingency management ($1 per completed weighing) will be used to facilitate adherence to this weighing schedule.

An innovative aspect of this treatment is helping patients develop alternative reinforcements that do not involve food that can reduce the motivation to eat for the hedonic or reinforcing motivations. The first step is to identify alternative activities that have a higher reinforcement value than the patients' favorite foods. First, participants will identify potential alternatives from the 139 behaviors on the Pleasant Activities List. The therapist then works with the patient to better specify the behavior, ensure its feasibility and describe the parameters of the behavior (e.g. duration). After the participant and case manager agree on a list of alternatives (at least 5), the participant will complete the Behavioral Choice Questionnaire that assesses the reinforcing value of that activity in comparison to food. The most reinforcing food to be used to assess behavioral substitutes will be chosen from a list of usual meals that can be obtained from home cooked, fast food or casual dining restaurants. These alternative reinforcements are used non-contingently by the patients/parents to provide highly desirable activities that compete with excessive food consumption.

6.2 Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those

drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

- *If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.*

Response: NA, the medication that patients are taking will be managed by their physician and only be a screening criteria.

6.3 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

- *Identify the holder of the IND/IDE/Abbreviated IDE.*
- *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

Response: NA

7.0 Local Number of Subjects

7.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.

Response: 30 participants, made of 15 patient and family member dyads, will be enrolled. Each one of the participants must have a household family member willing to collaborate in the program.

7.2 If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate).

Response: We expect to screen approximately 50-75 individual patients in order to recruit 12 patient and family member dyads who complete 75% of their visits.

We are planning to enroll 15 dyads, but anticipate that 3 will not complete 75% of their visits.

7.3 Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response: The NAVIGATE program admits 2 to 3 patients per month. At the beginning of the study, we anticipate that there would be approximately 40-45 patients in the program with the requisite use of antipsychotic medications, and over the next five months, we would expect an additional 10-15 patients. Assuming that 50% of the patients are eligible and interested, we would have approximately 25-30 patients available for the study.

8.0 Inclusion and Exclusion Criteria*

*8.1 Describe the criteria that define who will be **included** in your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

Participant:

-Age 14-26 years

-Enrolled in NAVIGATE, a clinical program for patients with first episode of psychosis.

-Prescribed antipsychotic medication for a first break psychotic episode

-Availability of household family member to collaborate in the weight management program.

Family Member:

-Lives in the same household as participant (e.g., parent, guardian, grandparent, aunt or uncle)

-Able to attend weekly meetings with a case manager

*8.2 Describe the criteria that define who will be **excluded** from your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

Participant & Family Member:

-Personal or Family history or evidence of current eating disorders (bulimia or anorexia or binge eating disorder)

- Current alcohol or drug abuse,

- Unable to read at 8th grade level

- Unable to use technology.

-Unable to weigh themselves daily due to existing medical condition

-Pregnant or planning on becoming pregnant during the study

8.3 Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.

NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.

Response:

☐ Adults unable to consent

☒ Individuals who are not yet adults (infants, children, teenagers)

☐ Pregnant women

☐ Prisoners

8.4 Indicate whether you will include non-English speaking individuals in your study. ***Provide justification if you will exclude non-English speaking individuals.***

In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may ***not*** *be routinely excluded from research as a matter of convenience.*

In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.

Response:

Participants must be able to read English at 8th grade level in order to complete questionnaires. English version surveys and complex instructions make enrolling non-English speakers impractical within this budget.

9.0 Vulnerable Populations*

If the research involves special populations that are considered vulnerable, ***describe the safeguards included to protect their rights and welfare.***

NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.

9.1 For research that involves ***pregnant women,*** *safeguards include:*
NOTE CHECKLIST: Pregnant Women (HRP-412)

Response:

☒ **N/A**: This research does not involve pregnant women.

9.2 For research that involves ***neonates of uncertain viability or non-viable neonates,*** *safeguards include:*
NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)

Response:

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

9.3 For research that involves ***prisoners****, safeguards include:*
NOTE CHECKLIST: Prisoners (HRP-415)

Response:

☒ **N/A:** This research does not involve prisoners.

9.4 For research that involves ***persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")****, safeguards include:*
NOTE CHECKLIST: Children (HRP-416)

Response:

☐ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

9.5 For research that involves ***cognitively impaired adults****, safeguards include:*
NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)

Response:

☒ **N/A:** This research does not involve cognitively impaired adults.

9.6 Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. ***Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Response: NA

10.0 Eligibility Screening*

*10.1 Describe **screening procedures** for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).

Response: All patients in NAVIGATE meet the inclusion criteria of first episode psychosis because it is a criteria for program entry. These patients are almost always on an antipsychotic medication. Co-investigator Dr. Zhanna Elberg, who is the director of the NAVIGATE program, will determine from medical records whether patients meet criteria for age and antipsychotic medication. She will also determine whether the patient has a substance use disorder or an eating disorder on the basis of the medical records. Dr. Elberg will determine if the patient and a family member involved in the treatment would be interested in the program. Interested patients and family members will be asked to sign a permission form for the research staff to contact them by phone. Research staff will contact the patient and family member, describe the program, determine their continued interest, and screen the family member with respect to residing with the patient, willingness to participate in the program activities. They will also screen the family member with respect to current substance use, ability to use technology, ability to weight themselves daily, and if female, whether they are currently pregnant or planning to be. Demographic factors including education will be assessed. If patients or family members did not complete high school, they will be told that there are written materials and they will need to complete a brief reading assessment at the first session.

☐ **N/A:** There is no screening as part of this protocol.

Recruitment Methods

☐ **N/A:** This is a records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections.

10.2 Describe when, where, and how potential subjects will be recruited.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g. searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.)

Response: Potential patients and parents in the NAVIGATE program will be identified by the director and clinical staff and will describe the availability of a weight management program designed to help patients maintain a healthy weight

or lose weight. If they are interested, the patient and family member will sign a permission form to provide contact information to the research staff.

10.3 Describe how you will protect the privacy interests of prospective subjects during the recruitment process.

NOTE: Privacy refers to an individual's right to control access to him or herself.

Response: Only patients who indicate an interest in participating will be contacted by the research assistant. All identifying information about participants and parents who are not eligible or who choose not to participate will be deleted.

10.4 Identify any materials that will be used to recruit subjects.

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

Response: NA

11.0 Procedures Involved*

*11.1 Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response.

Response: Participants and a household family member will have a baseline session. In this session, they will be asked to sign the consent and assent forms. They will be given a brief reading test to ensure they can read at the 8th grade level. They will then complete the Behavioral Choice Questionnaire that assesses the reinforcing value of food. They will also complete questionnaires regarding time perspective, consideration of future consequences, and have their height and weight measured.

Following the baseline assessment, daily weights will be collected over a two month period, and then families will be randomized to staggered initiation of treatment in blocks of 4 families. A Bluetooth scale will be provided.

Families will receive a 12-week FBT adapted for first episode psychosis. This will be delivered in 12 weekly meetings with a trained case manager and two "eating plan" education sessions. Both the patient with psychosis and parents are targeted for eating and activity/exercise change to ensure a change in the shared family environment, which will also help weight control in both sets of participants, as well as medical issues that accompany obesity, including glycemic control, hypertension and hyperlipidemia. If parents are not overweight/obese, they will still target improved health behaviors. They will learn about GREEN, YELLOW, and RED foods (healthy vs. unhealthy foods), energy density, glycemic index of foods, reducing serving sizes, eating less, healthy lifestyle and programmed activity programs and recording their diets and activity. Weekly sessions will involve discussion of weight loss principles presented in modules in the weight control manual, and coaching parents and patients how to implement the Traffic Light Eating Plan and healthy lifestyle techniques. At each session, participants meet with staff and attend a brief problem solving session with their case manager where they will troubleshoot any expected or encountered issues with implementing the program. As part of treatment, participants will weigh themselves daily with a Bluetooth scale. Contingency management ($1 per completed weighing) will be used to facilitate adherence to this weighing schedule.

An innovative aspect of this treatment is helping patients develop alternative reinforcements that do not involve food that can reduce the motivation to eat for the hedonic or reinforcing motivations. The first step is to identify alternative activities that have a higher reinforcement value than the patients' favorite foods. First, participants will identify potential alternatives from the 139 behaviors on the Pleasant Activities List. The therapist then works with the patient to better specify the behavior, ensure its feasibility and describe the parameters of the behavior (e.g. duration). After the participant and case manager agree on a list of alternatives (at least 5), the participant will complete the Behavioral Choice Questionnaire that assesses the reinforcing value of that activity in comparison to food. The most reinforcing food to be used to assess behavioral substitutes will be chosen from a list of usual meals that can be obtained from home cooked, fast food or casual dining restaurants. These alternative reinforcements are used non-contingently by the patients/parents to provide highly desirable activities that compete with excessive food consumption.

At the end of treatment, the patient and family member will receive the same assessment battery that they completed for the baseline session. They will also provide information on the implementation of the diet, exercise, and alternative reinforcement procedures.

After an additional 2 months, the patient and family member will return for the final assessment using the same assessment battery, as well as the

implementation data. Families will be compensated for completing the assessment, sign their payment form, and be debriefed.

11.2 Describe what data will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response: The primary data collected will be daily weight, which will be taken with a Bluetooth scale that they will be given by the project. This data will be collected throughout the 2 month baseline, 3 month intervention, and 2 month follow up.

At the beginning of the baseline, and the end of treatment, and at the end of the follow-up patients and parents will complete a questionnaire including the Behavioral Choice Questionnaire, and scales regarding parenting, time perspective, and consideration of future consequences.

11.3 List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).

Include copies of these documents with your submission.

Response: Behavioral Choice Questionnaire, Consideration of Future Consequences Scale, Zimbardo Time Perspective Inventory, Demographic Form for Participant and Family Member

11.4 Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).,

Response: The identified patients' medical records at Erie County Medical Center (Meditech) will be accessed to confirm antipsychotic medications, antipsychotic medications start date and dose, changes in dose, and other changes in medication. Comorbid medical conditions and medications will also be recorded. The EMR may be accessed throughout the study to confirm any antipsychotic dosing changes and weight at clinic visits (if participant is non-compliant with daily weigh-ins). In addition, HDL, LDL, Triglycerides, Total cholesterol and AC1 information will be gathered from the records throughout the baseline, treatment, and follow-up periods.

*11.5 Indicate whether or not **individual** subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe how these will be shared.*

Response: The participants will be aware of their test results because they will be weighing themselves daily.

*11.6 Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response: Study results will be shared with the patients and their parents at the end of the follow-up. These will be shared with a letter and an invitation to contact one of the study team members (Dr. Elberg or Dr. Antonius) for any questions. The aggregate data will be presented at conferences and in publications and other presentations.

12.0 Study Timelines*

12.1 Describe the anticipated duration needed to enroll all study subjects.

Response: We expect to enroll all study subjects within 6 months.

12.2 Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.

Response: Participants will be involved in the study for a total of up to 9 months. They will have 3 in person assessments, and 12 weekly interventions via zoom or or in person. The assessments and the weekly interventions will take approximately 1 hour.

While we expect participation to be completed in 7 months (2 months baseline, 3 months treatment, 2 months follow-up), we are allowing extra time for the rescheduling of missed appointments, etc.

12.3 Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).

Response: We expect to be able to complete the analyses within 6 months of the final follow-up assessment.

13.0 Setting

13.1 Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."

Response: The assessments and interventions will be conducted at the NAVIGATE clinic at Erie County Medical Center. Private offices are available for the assessments and interventions.

13.2 For research conducted outside of UB and its affiliates, describe:

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

NOTE: This question is referring to UB affiliated research taking place outside UB, i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.

Response:

☒ **N/A:** This study is not conducted outside of UB or its affiliates.

14.0 Community-Based Participatory Research

14.1 Describe involvement of the community in the design and conduct of the research.

NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

Response:

☒ **N/A:** This study does not utilize CBPR.

14.2 Describe the composition and involvement of a community advisory board.

Response:

☒ **N/A:** This study does not have a community advisory board.

15.0 Resources and Qualifications

*15.1 Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.

Response: PI Antonius has conducted extensive research with patient experiencing their first episode of psychosis. Co-I Elberg is the director of the NAVIGATE program and has extensive clinical experience with this population. Co-I Leonard has conducted numerous longitudinal studies examining families and different health behaviors, including substance use. Dr. Leonard Epstein, Co-I, has developed the Family Based weight management program and has many years of research examining weight loss and weight management programs. PC Colleen Kilanowski has served as a therapist and has supervised other therapists conducting the weight loss program.

Describe other resources available to conduct the research.

15.2 Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.

Response: PI Antonius will devote 20% effort to the project, Co-I Leonard will devote 10% effort. Co-Is, Epstein, Kilanowski, and Elberg will each devote 5% effort.

15.3 Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.

NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.

Response: It is not expected that subjects will require additional medical or psychological resources as a result of participating in this research. NAVIGATE patients are expected to maintain their normal psychiatric care.

15.4 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response:
A project manual describe the processes and procedures will be developed for training purposes. Dr. Antonius and Leonard will train staff assisting in the assessment. The therapist who conducts the intervention has been conducting similar interventions in Dr. Epstein's research program for more than 10 years.

15.5 Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).

Response: Approval from ECMC will be required after IRB approval.

☐ **N/A:** This study does not require any other approvals.

16.0 Provisions to Protect the Privacy Interests of Subjects

16.1 Describe how you will protect subjects' privacy interests during the course of this research.

NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

Response: Study visits take place via telemedicine or in a private room. Subject's data is shared with research staff as needed.

16.2 Indicate how the research team is permitted to access any sources of information about the subjects.

*NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question **does apply** to records reviews.*

Response: Participants (patients, parents or household members) ages 18 and over will sign a consent form. For participants ages 14-17, parents will sign a parental permission form and adolescents will sign an assent form.

17.0 Data Management and Analysis*

17.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Response: The project is a multiple baseline single case experimental design, with a 2 month baseline data collection. Families will then be randomized to staggered initiation of treatment in blocks of 4 families. We anticipate having 8 participating families at the

beginning of the project and would randomly assign them to start the baseline assessment between 1 and 9 weeks into the project, with the treatment then beginning between weeks 9 and 17. Treatment completion for this initial cohort would be between weeks 21 and 29, and the final follow-up would occur between weeks 29 and 37. Families entering NAVIGATE after the recruitment of the first cohort will be randomly assigned to start the baseline from 1 to 9 weeks after entry. This will provide a significant baseline (2 months) for all participants with different initial points for the study.

Analysis of the daily weights will involve discontinuous growth curve analysis using multi-level modeling (Singer and Willet, 2003). Separate models are developed for each participant which include the daily weights from the baseline (60 days), treatment (90 days) and follow-up (60 days) phases. Given the nature of the data, we would hypothesize significantly different slopes for the baseline vs treatment phases. We would also expect no significant differences between the slopes for the treatment phase and the follow-up phase. The primary analysis involves modeling each individual as a level one variable.

17.2 If applicable, provide a power analysis.

NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

Response: NA

17.3 Describe any procedures that will be used for quality control of collected data.

Response: Data will be reviewed by trained and IRB approved study personnel.

18.0 Confidentiality*

A. Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality of **study data and any records that will be reviewed for data collection**.*
A

*18.1 A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) **and** electronic files.*

Response: Paper information (questionnaires, consent forms) will be transported by Dr. Antonius to his ECMC office and stored in a locked filing cabinet. The master list linking participant identification and study ID will be kept in a separate

locked file in his office. Electronic data will be stored in a secure UB BOX folder. Drs. Antonius, Leonard, and Epstein will have editor privileges, the research assistant will have read privileges of the de-identified master data file.

18.2 A. How long will the data be stored?

Response: IRB correspondence will be maintained for three years after the closure of the study. The Master ID list will be deleted as soon as all of the participants have completed final data collection. The working data files will be stored for three years after the completion of the study or the publication of the results, whichever is later.

18.3 A. Who will have access to the data?

Response: Drs. Antonius, Leonard, and Epstein will have access to the data. A graduate student with statistical qualifications will also have access to the data for analysis.

18.4 A. Who is responsible for receipt or transmission of the data?

Response: A research assistant will collect the self report data and store it in UB BOX. The daily weight data will be collected by an app and uploaded to UB BOX.

18.5 A. How will the data be transported?

Response: Paper data will be transported by Dr. Antonius to his office. Electronic data will be uploaded from password protected computer at the clinic to UB BOX.

B. Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of **study specimens**.*

☒ **N/A:** No specimens will be collected or analyzed in this research. *(Skip to Section 21.0)*

18.6 B. Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.

Response:

18.7 B. How long will the specimens be stored?

Response:

18.8 B. Who will have access to the specimens?

Response:

18.9 B. Who is responsible for receipt or transmission of the specimens?

Response:

18.10 B. How will the specimens be transported?

Response:

19.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.

19.1 Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Response: Participants in this study continue with their regular psychiatric appointments along with this additional intervention. Assessing the weight of patients on antipsychotic medications is part of the treatment guidelines for patients on these medications.

19.2 Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response: Weights will be monitored weekly by the case manager.

19.3 Describe any safety endpoints.

Response: NA

19.4 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response: NA

19.5 Describe the frequency of safety data collection.

Response: NA

19.6 Describe who will review the safety data.

Response: See section 20.2.

19.7 Describe the frequency or periodicity of review of cumulative safety data.

Response: NA

19.8 Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response: NA

19.9 Describe any conditions that trigger an immediate suspension of the research.

Response: NA

20.0 Withdrawal of Subjects*

☐ **N/A:** This study is not enrolling subjects. This section does not apply.

*20.1 Describe **anticipated** circumstances under which subjects may be withdrawn from the research without their consent.*

Response: Participants who leave the NAVIGATE program or experience a psychotic relapse requiring hospitalization longer than one week will be removed from the study. Parents or support participants of the withdrawn participant may continue the study.

20.2 Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response: A final phone call with the participant and/or family member will take place. Arrangements to collect the Bluetooth scale will be made.

20.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response: No further treatment or assessments will be conducted on the withdrawn participant. However, any participant that is still willing to participate can continue the study. Data will be maintained for participants who remain in the study through 50% of the weight intervention program. Data for participants who withdraw sooner will also be retained for comparison to those who complete the intervention with respect to response to treatment.

21.0 Risks to Subjects*

21.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response: The primary risk to participants is the breach of confidentiality. Participants will be assessed and treated within an existing clinic setting from an experienced therapist. Given the strict maintenance of confidentiality in these clinic settings, this risk is very low.

21.2 Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

Response: Research staff who collect consent forms and assess the patients will be trained in the ethical treatment of research participants, with a particular focus on some challenging confidentiality issues, particularly if they know the participant. Under these circumstances, another individual will be responsible for collecting information and consenting the participants and their participating family member.

*21.3 If applicable, indicate **which procedures** may have risks to the subjects that are currently unforeseeable.*

Response: Participants may feel uncomfortable answering some of the sensitive questions about their health and decisions. Participants may experience hunger

from changes to eating patterns and possible discomfort to changes in physical activity.

21.4 If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response: N/A

21.5 If applicable, describe risks to others who are not subjects.

Response: NA

22.0 Potential Benefits to Subjects*

22.1 Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.

*NOTE: Compensation **cannot** be stated as a benefit.*

Response: Patients who are prescribed antipsychotics often gain significant weight and commonly stop the medication as a result. This can precipitate further psychotic episodes. A program that mitigates the weight gain can improve the health of the patient and the family member (reduced health risks associated with obesity) and reduce the potential for a relapse (which can have multiple social and physical consequences).

23.0 Compensation for Research-Related Injury

☒ **N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

*23.1 **If the research procedures carry a risk of research related injury,** describe the available compensation to subjects in the event that such injury should occur.*

Response:

23.2 Provide a copy of contract language, if any, relevant to compensation for research related injury.

*NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with **different language regarding research related injury**, you must modify your response here and submit an amendment to the IRB for review and approval.*

Response:

24.0 Economic Burden to Subjects

24.1 Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking.

Response: Participants will have travel and parking costs. Payments received for participation in research are considered taxable income.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

25.0 Compensation for Participation

27.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Response: Patients and parents will receive one dollar for each day that they submit a weight measurement during the study, for a maximum of $210 each. They will also receive $25 each for each of the 3 assessments.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

☐ **N/A:** There is no compensation for participation. This section does not apply.

26.0 Consent Process

26.1 Indicate whether you will be obtaining consent.

NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study. Consent documentation is addressed in Section 29.0.

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*

☐ ***No*** *(If no, Skip to Section 29.0)*

26.2 Describe where the consent process will take place. Include steps to maximize subjects' privacy.

Response: The participant and the family member will be consented separately in a private office in the clinic. The patient will be consented first, and if the patient agrees, the family member will then be consented.

26.3 Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.

NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-090)" Sections 5.5 and 5.6.

Response: Potential subjects will be offered the opportunity to participate in the trial. If interested, research staff will review the consent form with potential subjects at their convenience. Potential subjects are encouraged to review the consent form and are permitted to take a copy home/keep a copy for review prior to signing. Potential subjects are also encouraged to discuss participation with their primary care doctor or treating psychiatrist.

26.4 Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.

Response: Ongoing consent will be assessed at the weekly sessions.

26.5 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." Pay particular attention to Sections 5.4-5.9. If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:

- *The role of the individuals listed in the application who are involved in the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that will be taken to minimize the possibility of coercion or undue influence*
- *Steps that will be taken to ensure the subjects' understanding*

Response:

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

Non-English Speaking Subjects

☒ **N/A:** This study will not enroll Non-English speaking subjects. *(Skip to Section 28.8)*

26.6 Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

NOTE: The response to this Section should correspond with your response to Section 8.4 of this protocol.

Response:

26.7 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language, how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study, and any process to ensure ongoing consent. Indicate the language that will be used by those obtaining consent.

NOTE: Guidance is provided on "SOP: Informed Consent Process for Research (HRP-090)."

Response:

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults.
(Skip to Section 28.9)

26.8 Describe the process to determine whether an individual is capable of consent.

Response:

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent.
(*Skip to Section 28.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 28.9 and 28.10) ***and, where possible, assent of the individual should also be solicited*** *(Sections 28.11 and 28.12).*

26.9 Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.

NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.

Response:

☐ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

26.10 ***For research conducted outside of New York State****, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

26.11 Describe the process for ***assent of the adults****:*

- *Indicate whether assent will be obtained from all, some, or none of the subjects.* ***If some, indicate which adults will be required to assent and which will not.***

Response:

- ***If assent will not be obtained from some or all subjects, provide an explanation of why not.***

Response:

26.12 Describe whether ***assent of the adult*** *subjects will be documented and the process to document assent.*

NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the "Template Consent Document (HRP-502)" Signature Block for Assent of Adults who are Legally Unable to Consent.

Response:

Subjects who are not yet Adults (Infants, Children, and Teenagers)

☐ **N/A**: This study will not enroll subjects who are not yet adults. *(Skip to Section 29.0)*

26.13 Describe the criteria that will be used to determine ***whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research*** *under the applicable law of the jurisdiction in which the research will be conducted* ***(e.g., individuals under the age of 18 years)****. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.

Response: Patient's age is noted in the clinical record. Dr, Elberg will inform research staff is a patient is under the age of 18.

26.14 ***For research conducted outside of New York State****, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

26.15 Describe whether parental permission will be obtained from:

Response:

☒ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☐ Parent permission will not be obtained. A waiver of parent permission is being requested.

NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."

26.16 Describe whether permission will be obtained from individuals ***other than parents****, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response: Permission will be sought from parents or legal guardians. As the patient's clinical provider, Dr. Elberg will have information as to who has the authority to consent to the adolescent's health care. This information will be provided to the research staff at the time of referral.

26.17 Indicate whether assent will be obtained from all, some, or none of the ***children****. If assent will be obtained from some children, indicate which children will be required to assent.*

Response: Assent will be obtained from any children participating in the study.

26.18 When assent of children is obtained, describe how it will be documented.

Response: At the time of the consent procedure, patients and parents will be separated. The patient will be asked to sign the assent or consent form, and provided the patient signs, the parent will then be asked to sign the consent form.

27.0 Waiver or Alteration of Consent Process

Consent will not be obtained, required information will not be disclosed, or the research involves deception.

☒ **N/A:** A waiver or alteration of consent is not being requested.

27.1 If the research involves a waiver or alteration of the consent process, please review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.

NOTE: For records review studies, the first set of criteria on the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" applies.

Response:

27.2 If the research involves a waiver of the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response:

28.0 Process to Document Consent

☐ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 31.0)

28.1 Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as 'verbal consent.' Review "CHECKLIST: Waiver of Written

Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.

If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).

Response: We will follow SOP for written documentation of consent.

☒ We will be following "SOP: Written Documentation of Consent" (HRP-091).

29.0 Multi-Site Research (Multisite/Multicenter Only)*

☒ **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

29.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.

Response:

*29.2 If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as the following.*

- *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately in accordance with applicable federal regulations and local laws.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response:

29.3 Describe the method for communicating to engaged participating sites.

- *Problems (inclusive of reportable events)*
- *Interim results*

- *Study closure*

Response:

*29.4 If this is a multicenter study **where you are a participating site/investigator**, describe the local procedures for maintenance of confidentiality.*

- *Where and how data or specimens will be stored locally?*
- *How long the data or specimens will be stored locally?*
- *Who will have access to the data or specimens locally?*
- *Who is responsible for receipt or transmission of the data or specimens locally?*
- *How data and specimens will be transported locally?*

Response:

29.5 If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described elsewhere in the protocol.

- *Describe when, where, and how potential subjects will be recruited.*
- *Describe the methods that will be used to identify potential subjects.*
- *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*

Response:

30.0 Banking Data or Specimens for Future Use*

☒ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

*30.1 If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the data/specimens will be stored, how long they will be stored, how the*

data/specimens will be accessed, and who will have access to the data/specimens.

NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).

Response:

30.2 List the data to be stored or associated with each specimen.

Response:

30.3 Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Response: