Uniformed Services University of the Health Sciences
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Bethesda MD 20814-4799

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9300 DeWitt Loop
Fort Belvoir VA 22060

INFORMED CONSENT FORM RESEARCH STUDY

PREVENTION GROUP: PARENT FOR CHILD

Preventing Obesity in Military Communities - Adolescents

This consent form is valid only if it contains the "USU IRB Approved" stamp. Do **not** sign this form or participate in this research if the IRB stamp is not present or if it has expired.

INTRODUCTION

You and your child are being asked to take part in a research study. Dr. Marian Tanofsky-Kraff is the Principal Investigator for this study. Before you decide if you want you and your child to be in the study, it is important for you both to understand the risks and benefits so that you can make an informed decision. This is known as informed consent.

This consent form provides information about the research study, which has been explained to you. Once you understand what it involves, you will be asked to tell the researcher if you and your child want to take part in it. Your and your child's decision to take part in the study is entirely voluntary. This means that you and your child are free to choose whether or not you want your child to be a research subject.

DESCRIPTION OF THE RESEARCH AND ITS PURPOSE

The Uniformed Services University of the Health Sciences has partnered with the Fort Belvoir Community Hospital (FBCH) in Fort Belvoir, VA, Kimbrough Ambulatory Care Center (Kimbrough) in Fort Meade, MD the Walter Reed National Military Medical Center (WRNMMC) in Bethesda, MD, and Malcolm Grow Medical Clinic (MGMC) at Andrews Air Force Base, MD to conduct a research study aimed at the prevention of excessive weight gain in youth military dependents at high risk for adult obesity. Your child has been identified as possibly being at high risk for adult obesity. Obesity puts individuals at risk for medical problems such as high blood

pressure, heart disease, type 2 diabetes mellitus (sugar diabetes), sleep apnea (trouble breathing while sleeping), joint disease, and certain forms of cancer. Obesity also is associated with a number of psychological problems including social difficulties, eating disorders, depressive symptoms, and poor quality of life.

Military dependents ages 12 to 17 years are included in this study. All participants must have a body mass index (BMI), which is a calculation that takes into account a person's height and weight, at or above the 85th percentile for their age. A percentile means that we are comparing a youth's BMI to the BMI of all other youth their age and gender. Being at or above the 85th BMI percentile means that youth are at risk for adult obesity. Also, all youth must have experienced either a feeling of loss of control over their eating during the 3 months prior to the baseline screening assessment or report anxiety symptoms. There will be up to 212 youth taking part in this study. Initial and follow-up assessments will take place at FBCH and USU. Groups will be held at four locations: FBCH, USU Kimbrough, and MGMC.

Interpersonal Psychotherapy (IPT) is a time-limited, group program effective for the prevention and treatment of depression in youth. It also is effective for the treatment of binge eating and has resulted in preventing excess weight gain in civilian youth. We have adapted the IPT program for youth military dependents. The delivery of IPT to youth in military families who are at high risk for adult obesity has been shown to be acceptable. IPT focuses on improving how youth get along with the important people in their lives so that they feel better about themselves. By feeling better, we expect them to be less likely to feel loss of control over their eating or to use food to cope when feeling stressed or upset. Research results suggest that IPT programs are well accepted and may be useful for improving eating behaviors in adults from racial/ethnic minority backgrounds. Therefore, we hope that participation in IPT will reduce military dependent youths' risk for excess weight gain and adult obesity.

There are three parts to this study. The first part consists of a screening visit that will take approximately 5 hours to complete. If you and your child prefer, we are able to split this screening visit into two visits. During the screening, we will find out if your child is able to take part in the study, and we will let you know afterwards whether your child qualifies for the study. During the screening, we will also ask you to fill out some questionnaires about yourself, your child, and your family. These questionnaires take about 1 hour to complete. However, if you do not wish to complete these questionnaires for any reason, this would not prevent your child from participating in the study if your child is interested and eligible.

In the second part of the study, youth who are eligible and choose to participate will be randomly assigned to either an IPT group or to a health education group. Boys and girls will be placed in separate groups. You and your child would need to agree to be randomly assigned to either IPT or

the health education group in order to participate in this study.

For your convenience, you may choose whether your child will attend the weekly group sessions in Fort Belvoir, VA (FBCH), Bethesda, MD (USU), Fort Meade, MD (Kimbrough), or Joint Base Andrews, Maryland (MGMC). Once your child starts the IPT or health education group, he or she will need to come to FBCH, USU, Kimbrough or MGMC weekly for 13 weeks. The first week will involve a 1.5-hour individual visit with the group leader(s), and the next 12 weeks will involve 1.5-hour group meetings with approximately 4 other same-gender youth. After the groups, we will compare the body weight, laboratory blood values, eating behavior, and mood of youth who take part in the IPT group to the weight, eating behavior, and mood of the youth who take part in the health education group.

The third part of the study will involve 2 follow-up visits. Follow-up visits will take place at FBCH, or USU, depending on what is most convenient for you. The first visit will take place within 1-2 weeks following the last group session. The second follow-up visit will take place about 1 year after the first group session. At 2 and 3 years following the start of the study, we will contact you to remind you to visit your healthcare provider so that we can obtain your child's height and weight data, blood pressure, and blood values through AHLTA (Armed Forces Longitudinal Technology Application), the electronic medical records system used by medical providers of the U.S. Department of Defense. We will also ask your child some questions about any additional treatments or medications he/she may have received since their last visit. If you and your child are no longer receiving care through the Tricare system at any point during the duration of the study, or you and your child are unable to access a Tricare clinic due to relocation, we will contact you to arrange for a nurse at Encore Medical Staffing Incorporated (EMSI) to come to your home (or an agreed upon location) to collect height, weight, blood pressure and a blood sample from your child. EMSI is a safe and secure medical records retrieval company. EMSI will travel to your home and obtain your child's measurements and a blood sample at your convenience. If you do not feel comfortable with an EMSI nurse coming to your home, an alternative location can be agreed upon that is convenient for you. Any sample obtained through EMSI will be sent directly to USUHS for storage and de-identification. If you and your child opt to use EMSI versus a Tricare facility to complete the follow-up procedures, we will not be able to notify you of your child's blood results.

PROCEDURES OF THE STUDY

Screening Appointment

You and your child will need to arrive at FBCH or USU in the morning for the screening appointment, which will take about 5 hours to complete. We will ask that your child not have

anything to eat after 10:00 pm on the night before coming to this appointment. You will need to accompany your child on this visit. During the screening visit, we will do the following things:

1. Consent. We will go over this consent form in detail, review all parts of the study, and if you and your child choose to participate, we will ask you and your child to sign the consent and assent forms.

2. Body measurements. We will measure your child's height, weight, waist circumference, blood pressure, and body composition. We will analyze your child's body composition using a BodPod machine, which uses air displacement plethysmography to measure fat mass and fat-free mass. Your child will be asked to sit still inside the BodPod wearing a bathing suit for one minute while breathing into a plastic tube.

3. Fasting blood samples. We will draw a small amount of blood to be used exclusively for research purposes (no more than 5.5 mL at each visit), in addition to the standard of care labs (e.g. triglycerides, HDL cholesterol, and glucose). The standard of care labs will be analyzed to determine the presence of obesity-related comorbidities, such as high blood sugar. If your child tests positive for an obesity-related health problem, we will encourage him or her to visit their primary care provider. If we find anything unusual on these tests, we will inform you. The collected research sample will be de-identified and will be stored in a secure freezer in USU lab space for future analysis and kept for up to ten years.

4. Questionnaires and interviews. We will conduct questionnaires and interviews with your child about his or her current eating patterns and about his or her mood and psychological functioning. Specifically, we will ask you and your child to answer questions about his or her general health, social and psychological functioning and about how he or she eats. Your child will complete the questionnaires online securely. Some of the questions may be sensitive in nature (e.g., concerning body image, drinking/drug-use, depression). We are asking these questions to see how your child is doing, and to potentially refer your child for outside treatment should the need arise. We will also ask **you** to fill out several questionnaires about your child's functioning (e.g., any problems that he or she may be having, how well he or she gets along with peers, and his or her strengths and weaknesses), your own psychological health (e.g., feelings of stress, eating habits), and demographic information about your family. With the exception of one brief questionnaire, you may take these questionnaires home with you to complete if you prefer. If you choose to complete the questionnaires at home, a team member will provide you with a stamped and addressed envelope, or you may return the questionnaires in person at a later date. If you choose to fill out some or all of the questionnaires at home, we ask that you please fill them out individually, without the help of anyone else. Although we invite

all parents to complete these questionnaires, please note that you may refuse to complete any or all of these questionnaires, and this would not prevent your child from participating in the study.

All of this information (both yours and your child's) is kept confidential and will be protected to the fullest extent provided by law, unless we have a concern about your or your child's health or safety. **The proper authorities will be notified if information is revealed concerning harm to self or others, as well as homicide or child abuse or neglect. If you or your child feels uncomfortable answering any question, you or your child do not have to answer that question.** If you or your child demonstrate signs of clinical depression or other mental health concerns, and it is determined that you or your child will need further behavioral health or medical services, this will be accommodated through a health care professional in accordance with normal clinical standard of care. If there is evidence or signs of suicidality, you and/or your child will be immediately referred for a psychiatric consultation and referred for outside treatment as recommended (and excluded from participating in this study). If you or your child is in need of an urgent evaluation (e.g., actively suicidal with a plan to carry out such actions), an on-call health care professional will be contacted for an immediate consultation and intervention until you or your child can be safely referred for outside treatment.

IPT or Health Education Group

For participants who are assigned to IPT, there will be 1 individual pre-group session (approximately 1.5 hours) when your child will meet with the group leaders so that they can learn about your child's significant relationships, set goals for the program, and so your child can learn about group participation and format. Your child then will begin IPT for once a week, after school, for 12 consecutive weeks. IPT for the prevention of excess weight gain was designed to decrease excessive weight gain among youth ages 12-17 years who are at risk for adult obesity. The IPT program has been further adapted to be appropriate for military dependents. The IPT group involves 1.5-hour weekly group meetings for 12 consecutive weeks and involves developing strategies for dealing with the problems that youth struggle with that may lead to overeating. Although the majority of discussion tends to be about improving relationships with family or friends, topics such as romantic relationships, could arise. Leaders are trained to maintain an appropriate focus on reducing how certain moods can impact overeating. At about the 6th week of the group, the group leaders meet individually with your child (for about 15 minutes) to review his/her progress and goals. All participants, including your child, will be asked to maintain confidentiality with regard to group discussions and to not share any information learned about other group members outside of the group. The pre-group appointment and group sessions will take place at FBCH USU, Kimbrough, or MGMC. You and your child will be asked to select one

of these locations during the screening visit. Your child will only be able to attend sessions at the location you have selected.

The health education group will follow the "HEY-Durham" health program designed by researchers at Duke University. This program, designed to be delivered to youth attending community high schools, was adapted to a 12-week program (90 minutes per session). Your child will come in for a 1.5-hour group meeting once a week for 12 weeks (12 times total). There will also be 1 individual pre-group session (approximately 1.5 hours) when your child meets with the group leaders to review his or her family health history. The curriculum includes focus on various health topics, including avoiding alcohol, drug and tobacco use, nutrition and body image, nonviolent conflict resolution, sun safety, exercise, and domestic violence. There is no discussion of sexual activity or reproduction. All participants, including your child, will be asked to maintain confidentiality with regard to group discussions and to not share any information learned about other group members outside of the group. The pre-group appointment and group sessions will take place at FBCH USU, Kimbrough, or MGMC.

If your child's initial screening visit occurred more than 3 months prior to the start of the group program, during the pre-group meeting we will take another measurement of your child's height and weight. Additionally, a research coordinator will call him/her and administer a brief questionnaire and interview over the phone before the first group session. If your child is no longer eligible based on this re-assessment, then he/she will be excluded from participation in the study.

In the event that your child is unable to obtain transportation to a group session, the study team will provide and coordinate a taxi to take your child from home/school to their session and back.

Follow-up Assessments

Your child will be asked to return to FBCH or USU to be assessed at the conclusion of the groups, and again for one additional follow-up visit. The first follow-up visit will be 1-2 weeks after the program ends. The second follow-up will occur about 1 year following the start of the program. In the event that your child is unable to obtain transportation to a follow-up appointment, the study team will provide and coordinate a taxi to take your child from home/school to their appointment and back. At both follow-up visits, we will collect your child's body measurements, including height, weight, waist circumference, and blood pressure. We also will ask your child to answer questions about his/her general health, social, and psychological functioning and about how he or she eats. We will also draw a small amount of blood to be used exclusively for research purposes (no more than 5.5 mL at each visit), in addition to the standard care labs to repeat the same tests as done during the screening visit. We will collect the same information, excluding the body composition measurement and waist circumference, at 2-years and 3-years from the beginning of the group using information obtained through AHLTA. A research coordinator will contact you at

these 2- and 3-year time points to remind you to schedule a well-child visit with your healthcare provider and to ask your child a few more questions about any additional treatments he/she may have received since their last visit.

If prior to either of the in-person follow-up assessments your family or child leaves the area, resulting in too great a distance to travel to FBCH or USU, or your family or child is no longer enrolled in the TRICARE system, we will try to obtain follow-up information from you and your child using three methods: 1) we will contact you and your child by phone to ask your child a brief subset of the same questions that we asked during the baseline visit (e.g., we will ask your child questions about his or her recent eating behavior and general functioning), 2) we will send your child a secure link to SurveyMonkey or a physical questionnaire packet (with a self-addressed stamped envelope) to complete and return to us and 3) a physician on the research team will contact your new health care professional to have your child's standard of care labs drawn. A member of our study team who has access to the AHLTA system will access basic information about your child (e.g., height and weight, laboratory values). If your child completes this modified follow-up assessment (in the event of relocation) then he or she will be compensated in the same manner described below.

If your child is no longer covered by Tricare at any of the follow-up time points, or there is no convenient Tricare clinic for your child to visit, we will arrange for a staff member provided by EMSI to visit your child to collect height, weight, blood pressure and a small blood sample that will include the same blood tests as the standard of care labs. If you and your child opt to use EMSI to complete the follow-up procedures, we will not be able to notify you of your child's blood results.

If you or your child need a medical or psychiatric referral and are no longer covered by Tricare, a member of the study team will refer you to a provider outside of the Military Healthcare System.

If/when your child turns 18 during the course of the study, someone from the study team will contact him or her to obtain consent to continue participating in the study, either during a scheduled in-person visit to Fort Belvoir or USU, or remotely over the phone. At this time, we will go over the remaining study activities with your child. We will also ask your child to complete a new HIPAA authorization form if he or she turns 18 during the study timeline.

POSSIBLE BENEFITS

The potential benefit to your child from participation in this study is a reduction in the risk of gaining excess weight and an improvement in interpersonal functioning and increased knowledge with regard to living a healthier life. However, because we do not know how well the IPT program

or the health education group will work to help youth maintain or lose weight, there may be no direct benefit to your child, or the benefit may be only temporary. We do not expect there to be any direct benefit to you from completing study questionnaires.

COMPENSATION

Your child will be compensated for the time and inconvenience of participation. The schedule for the compensation is as follows: $50 for each of your child's in-person assessments (baseline, 12 week and one year follow-ups), with an additional "attendance bonus" of $50 if your child attends at least 10 of the 12 group sessions. Thus, the total possible amount of compensation for your child's full participation is $200.

Federal personnel who take part in this study while on duty cannot be paid. If you are a federal government employee participating in this study during your duty hours, you are encouraged to obtain permission from your commanding officer/supervisor.

In order to compensate your child, we will ask you to complete a brief IRS W-9 form and to provide your or your child's social security number. This information will be scanned and processed through secure file transfer. After confirmed receipt of the materials by the Henry Jackson Foundation Accounts Payable, the hard copy of this form will be expunged from your child's file. If you decline to provide your or your child's social security number, your child will be ineligible to be paid for their participation in the study.

POSSIBLE RISKS

1. Although very uncommon, some children experience lightheadedness or fainting during a **blood draw**. If your child has fainted in the past during or after a blood draw, please inform the Research Coordinator during the baseline appointment, so we can ensure that your child is as safe and comfortable as possible.

2. **Psychological testing** involves no risk, but may be inconvenient because of the time required for testing. You or your child may feel uncomfortable being asked about the way you feel about yourselves or about your relationships with others. Should any serious psychological or psychiatric condition be found, you and your child will be referred to an appropriate health care professional.

3. **IPT and Health Education Group** involve no physical risk, but topics that are personally sensitive will be discussed. Emotional distress is typically expected and often an important component necessary to make the changes required for improvements in social

functioning, mood and eating patterns. There also may be times where conflict occurs between group members and outside relationships. While stress and interpersonal conflict are emotionally difficult experiences and may cause distress for your child, it is often part of the process of making changes. The goal of the group leaders and the group as a unit is to support each participant through stressful periods in order to produce more satisfying relationships and healthier eating patterns. However, if there is evidence of the development of a psychiatric disorder or signs of suicidality, your child will be immediately referred for a consultation with a health care professional in accordance with normal clinical standard of care. If your child is in need of an urgent evaluation (e.g., is actively suicidal with a plan to carry out such actions) while on the FBCH, USU, Kimbrough sites, or MGMC sites, a health care professional will be contacted for an immediate consultation and intervention until your child can be safely referred for treatment.

4. While the goal of this study is to prevent excess weight gain or induce modest weight loss, your child may have **unrealistic expectations** of how much weight he or she might lose. Your child may imagine he or she will achieve significant weight loss after only a few months. Your child may experience disappointment, or may even become depressed, when this much weight loss does not happen. This is not a weight loss treatment study. Efforts will be made to help your child have realistic expectations regarding the expected impact of the IPT-WG program on his or her body weight.

5. The duration of this study is approximately 3 years, however, only the first year will require in-person visits. The **time required** for participants in either group is one 5-hour screening visit, one 1.5-hour individual pre-group meeting, twelve 1.5-hour IPT-WG group sessions, and two in-person follow-up appointments. All screening and follow-up appointments will take place at either the FBCH Family Medicine clinic or USU. All group and pre-group sessions will take place at either FBCH USU, Kimbrough, or MGMC. You will be asked to indicate which site you and your child have selected during the screening visit. The time required for you, the parent, includes the consenting process and the time needed to complete the questionnaires (about 2 hours total).

RIGHT TO WITHDRAW FROM THE STUDY

You or your child may decide to stop taking part in this study at any time. Your child's participation in this study also may be stopped by the investigators at any time, without your or your child's consent. Further, you or your child may withdraw from the study entirely at any time and request that we not contact you further (in which case we would not ask your child to participate in follow-up assessments). Alternatively, your child may choose to stop participating in the study groups,

but he or she will still be permitted to complete follow-up assessments if interested. That is, in the event that your child wishes to withdraw from study groups but remains interested in participating in follow-up visits, we will ask him or her to return for follow-up assessments and compensate him or her for completing assessments in the same manner as described above. Group participation and follow-up visits are completely voluntary, and you or your child can choose to withdraw from either or both at any time. If you would like to withdraw from the study at any time, please call Dr. Marian Tanofsky-Kraff at (301) 295-1482.

If your child withdraws from the study, we still keep his/her records, as outlined below. If you would prefer us to expunge your child's information from our records, please contact Dr. Marian Tanofsky-Kraff at (301) 295-1482

ALTERNATIVE PROCEDURES OR TREATMENTS

If investigators are aware of a treatment that may be more effective or appropriate than IPT-WG for your son/daughter's needs and/or symptoms, we will provide relevant information and referrals. Additionally, if your child tests positive for an obesity-related health problem, we will inform you and refer you and your child to his/her health care provider.

CONDITIONS UNDER WHICH PARTICIPATION IN THIS STUDY MAY BE STOPPED WITHOUT YOUR CONSENT

The study investigator may withdraw your child from the study without your consent for one or more of the following reason:

- Pregnancy
- Your child needs treatment beyond the scope of this study
- The study is cancelled
- Other administrative reasons
- Unanticipated circumstances

PRIVACY AND CONFIDENTIALITY

All information you and your child provide as part of this study will be confidential and will be protected to the fullest extent provided by law. There is one exception. **The proper authorities will be notified if information is revealed concerning harm to self or others.** In addition, concern regarding mental illness or suicidality will be handled as previously described:

{If you or your child demonstrate signs of clinical depression or other mental health concerns, and it is determined that you or your child will need further behavioral health or medical

services, this will be accommodated through a health care professional in accordance with normal clinical standard of care. If there is evidence or signs of suicidality, you and/or your child will be immediately referred for a psychiatric consultation and referred for outside treatment as recommended (and excluded from participating in this study). If you or your child is in need of an urgent evaluation (e.g., actively suicidal with a plan to carry out such actions), an on-call health care professional will be contacted for an immediate consultation and intervention until you or your child can be safely referred for outside treatment.}

Your and your child's responses to interviews and questionnaires, as well as audio-taped interviews and group sessions will be maintained in a locked filing cabinet in the research team's laboratory offices. All records related to this study will be accessible to those persons directly involved in conducting this study and members of the USU Institutional Review Board (IRB), the FBCH Department of Research Programs (DRP), the WRNMMC DRP, and the Henry M. Jackson Foundation Office of Regulatory Affairs and Research Compliance (HJF ORARC), who help oversee this study. In addition, the IRB/DRP at these locations and other federal agencies that help protect people who are involved in research studies may need to see the information you give us. Other than those groups, records from this study will be kept private to the fullest extent of the law. Scientific reports that come out of this study may include your ideas, but they will not use your or your child's name or identify you in any way. Additionally, records may be looked at by staff from the FBCH Department of Research Programs (DRP), the WRNMMC DRP, and the HJF ORARC.

All electronic and hard copy documents related to this protocol that contain Protected Health Information (PHI) are secured in accordance with the HITECH Act of 2009.

RECOURSE IN THE EVENT OF INJURY

This study should not entail any physical or mental risk beyond those described above. We do not expect complications to occur, but if, for any reason, you feel that continuing this study would constitute a hardship for you, we will end your participation in the study. If you think you have a study-related injury you should contact either the FBCH Office of the Command Staff Judge Advocate in the Sunrise Pavilion at (571) 231-2877 or the WRNMMC IRB Office (301) 295-8217. If you believe that you have suffered an injury or illness as a result of participating in this research project, you should contact FBCH Human Protections Administrator at (571) 231-2537, the Belleville Family Medicine Clinic Patient Advocate at (618) 256-7311 (4413), or the WRNMMC at (301) 295-8239.

IF YOU HAVE QUESTIONS OR CONCERNS

If you have questions about this research, you should contact Dr. Marian Tanofsky-Kraff at (301) 295-1482 or Dr. Mary K. Higgins Neyland at (301) 295-1872. Even in the evening or on weekends, you can leave a message at those numbers, although calls may not be returned until the following Monday. If you have questions about the study, contact the FBCH Investigator, Dr. Sarah Jorgensen, Family Medicine Department, (571)-231-1803, or the WRNMMC/USU Investigator, Dr. Jeffrey Quinlan, Family Medicine Department, (301)-295-9464. For questions about your and your child's rights as research participants, contact FBCH Human Protections Administrator in the Sunrise Pavilion at (571) 231-2537 or the USU IRB at (301)-295-9534. If you consent to your child participating in this study, but you yourself do not wish to participate, you may elect to sign in the second section below to indicate this.

By signing this form you are agreeing that this study has been explained to you and that you understood that explanation.

By signing here, I consent for both my child and myself to participate in this research study.

_____	_____
Parent/Guardian	Date of signature
_____	_____
Child Subject	Date of signature
_____	_____
Witness	Date of signature

By signing here, I consent for **only** my child to participate in this research study.

Parent/Guardian	Date of signature
Child Subject	Date of signature
Witness	Date of signature

Please indicate below which site you and your child have chosen.

This will be the site you come to for the initial screening visit and the in-person follow-up appointments:

- ☐ Fort Belvoir Community Hospital, Fort Belvoir, VA
- ☐ Walter Reed National Military Medical Center and the Uniformed Services University, Bethesda, MD

This will be the site you come to for the group sessions:

- ☐ Fort Belvoir Community Hospital, Fort Belvoir, VA
- ☐ Walter Reed National Military Medical Center and the Uniformed Services University, Bethesda, MD
- ☐ Kimbrough Ambulatory Care Center, Fort Meade, MD
- ☐ Malcolm Grow Medical Clinic, Joint Base Andrews, MD

I certify that the research study has been explained to the above individuals, by me or my research staff, and that the individual understands the nature and purpose, the possible risks and benefits associated with taking part in this research study. Any questions that have been raised have been answered.

_____ _____

Investigator Date of signature

Timeline and Summary of Youth's Participation in POMC-A Study
Screening appointment (about 5 hours)
Meet at FBCH or USU
Consent review
Body measurements, Blood draw
Questionnaires and interview
Individual pre-group meeting (about 1.5 hours)
Meet individually with group leaders at FBCHUSU, Kimbrough, or MGMC
IPT group sessions (12 weeks; *IPT participants only*)
Twelve 1.5 hour group sessions at FBCH USU, Kimbrough, or MGMC
Health Education (12 weeks; *Health Education participants only*)
Twelve 1.5 hour group sessions at FBCH USU, Kimbrough, or MGMC
12-week follow-up (about 2 hours)
Body measurements, Blood draw at FBCH or USU
Questionnaires and interview
1-year follow-up (about 2 hours)
Body measurements, Blood draw at FBCH or USU
Questionnaires and interview

AUTHORIZATION FOR RESEARCH USE OF PROTECTED HEALTH INFORMATION

The Federal Health Insurance Portability and Accountability Act (**HIPAA**) includes a Privacy Rule that gives special safeguards to Protected Health Information (**PHI**) that is identifiable, in other words, can be directly linked to you (for example, by your name, Social Security Number, birth date, etc.). We are required to advise you on how your PHI will be used. This authorization is effective until this study is closed.

(1) What information will be collected?
For this research study, one questionnaire will collect name, age, date, gender, interviewer name, and eating behaviors. On another questionnaire we will collect child's name & Medical Record #, clinician name & ID#, clinic, psychiatrist name, date, and information on depression, emotions, thoughts, mood, cigarette, alcohol, substance, or tobacco use, and sleep. On another questionnaire we will collect information on emotional problems, past diagnoses, and history of therapy. On another form we will collect ID/Subject #, date, name code, form completed by code, signature, and study week. On another form we will collect name, age, and date. On another form we will collect child's social security number. On other forms we will collect Patient ID, session number and date, group leader name, supervisor name, rater name, date of rating. We will also be collecting information on height, weight, metabolic markers, phlebotomy results, and blood pressure.

(2) Who may use your PHI within the Military Healthcare System?
The members of the research team will have access to your health information in order to find out if you qualify to participate in this study and to analyze the research data. Additionally, your PHI may be made available to health oversight groups such as the WRNMMC DRP, FBCH DRP, the USU IRB, and the HJF ORARC.

(3) What persons outside of the Military Healthcare System who are under the HIPAA requirements will receive your PHI?
No persons outside of the Military Healthcare System will receive PHI unless you no longer are enrolled in Tricare in which case we will use EMSI to collect height, weight, and a blood sample from your child.

(4) What is the purpose for using or disclosing your PHI?
The members of the research team need to use your PHI in order to analyze the study information.

(5) How long will the researchers keep your PHI?
The research team will keep the research data for up to six years after the end of the study. At that time all the information will be destroyed. The master code will be destroyed as soon as all data collection is completed. This assent or consent form and HIPAA authorization will be maintained for a period of six years after the study is completed.

(6) Can you review your own research information?
You will not be able to look at your research information.

(7) Can you cancel this Authorization?

Yes. If you cancel this Authorization, however, you will no longer be included in the research study. The information we collected from you can be destroyed at your request. If you want to cancel your Authorization, please contact the Principal Investigator in writing.

(8) What will happen if you decide not to grant this Authorization?
If you decide not to grant this Authorization, you will not be able to participate in this research study. Refusal to grant this Authorization will not result in any loss of medical benefits to which you are otherwise entitled.

(9) Can your PHI be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?
There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your PHI include representatives of the DOD Higher Level Review, the Food and Drug Administration, the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), and the DHHS Office for Civil Rights. This disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule.

(10) Who should you contact if you have any complaints?
If you believe your privacy rights have been violated, you may file a written complaint with the (1) FBCH Privacy Office, located at 9300 Dewitt Loop, Oaks Pavilion, Fort Belvoir, VA 22060 at 571-231-3319 or the (2) WRNMMC Department of Research Programs, located at 8901 Rockville Pike, Building 17B, 3rd Floor, Suite C, Bethesda, MD 20889 at (301) 295-8239 or the (3) USU Human Research Protections Program Office at 4301 Jones Bridge Road, Room A2051, Bethesda, MD 20814 at (301) 295-9534.

Your signature on the attached document acknowledges that you authorize FBCH, Kimbrough, MGMC and WRNMMC personnel to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.