Document Coversheet

Study Title: The Pediatric Oncology Interventional Nutrition Therapy (POINT) Trial: A Pilot Study

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KEY INFORMATION FOR
The Pediatric Oncology Interventional Nutrition Therapy (POINT) Trial: A Pilot Study"

We are asking your child to choose whether to volunteer for a research study about how your child's weight changes with diet changes during pediatric cancer treatment. We are asking your child because they have been diagnosed with a pediatric cancer and participation in this study is optional for all newly diagnosed cancer patients at the DanceBlue Pediatric Hematology and Oncology Clinic. This page will give you key information to help your child decide whether to participate. We have included detailed information after this page. Feel free to ask the research team questions. If your child has questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

During treatment for pediatric cancer, many patients will have changes in their weight. Diet changes to prevent weight loss are not well known on how it affects body changes in muscle and fat, or which treatment types are best. There are three options we usually can use: nutrition supplements, which are usually high-calorie drinks that can be added to your child's diet; appetite stimulants, which are medications given to boost your child's appetite; or what we call enteral feeds, which is feeding the child with a liquid formula through a tube that runs from their nose to their stomach. We don't know which of these options is best for helping children gain weight in a healthy way, and that is what this study is hoping to find out.
Body muscle and fat will be measured via quadricep ultrasound measurements. Body weight, height, and body mass index (BMI) will also be measured. Physical activity monitoring will be self-reported. Nutritional monitoring will be completed with 24-hr food logs. Lab draws to check your child's blood will occur during already scheduled lab draws when your child's central line (Port-a-Cath or other central line device) is already being accessed.

By doing this study, we hope to learn how body composition changes throughout therapy and how nutrition interventions alter body composition. Additionally, these results could tell us which nutrition interventions are the best to use during therapy. Your child's total time enrolled in this study will be between 6-12 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE FOR YOUR CHILD TO VOLUNTEER FOR THIS STUDY?
The options we have for helping to manage your child's weight are the same whether you choose to participate in the study or not. Participating in the study will allow us to learn which of these options is the best for children needing to gain weight during treatment for childhood cancer. It is unlikely your child will receive any direct benefit from taking part in this study. However, we hope that the information learned from this study will help us take better care of patients in the future.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO HAVE YOUR CHILD VOLUNTEER FOR THIS STUDY?
For patients with leukemia, there is a low likelihood that a tube would be needed for feeding during treatment. While some patients with leukemia struggle with weight loss and need help gaining weight again, most patients do not need a feeding tube to help them gain weight. Therefore, for patients with leukemia, being randomized to receive a feeding tube is something your child would be unlikely to experience if your child did not take part in this study. For patients with all other cancers, there is a moderate risk that your child may need a feeding tube at some point during treatment to help get them the best nutrition during time where treatment is intense, and eating is difficult. There is a risk that the placement of the tube from the nose to the stomach is uncomfortable for the patient. We do our best to work with the team that places the tube and our child life team to help minimize any discomfort. Any discomfort felt by having a tube in place is usually temporary and resolves quickly as your child gets used to the tube.
Blood draws obtained during this study will be done during times we would already be drawing blood, so there will not be additional sticks. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to allow your child to take part in the study, it should be because you really want them to serve as a volunteer and your child is willing to participate. Your child will not lose any services, benefits or rights he/she would normally have if you choose not to allow him/her to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw your child from the study contact Amanda Harrington MD or Corey Hawes Doctor of Clinical Nutrition of the University of Kentucky, Department of DanceBlue Pediatric Hematology/Oncology at cjhawe2@uky.edu.

If you have any concerns or questions about your child's rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOUR CHILD WOULD NOT QUALIFY FOR THIS STUDY?

Your child would not qualify if he/she is under the age of 2 or 18 and above at diagnosis. Other reasons include current use of tube feeding (enteral nutrition), oral nutrition supplement use, or medications that have an appetite stimulating effect.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at Kentucky Children's Hospital (KCH) and/or Kentucky Children's Hospital DanceBlue Pediatric Hematology/Oncology Clinic. Your child will need have ultrasound measurements and/or labs drawn at baseline (diagnosis), and then up to three times during the study. The study will take no longer than 12 months from diagnosis.

WHAT WILL YOUR CHILD BE ASKED TO DO?

If weight loss occurs during therapy, a patient is given diet treatments in a gradual way from least invasive to most invasive. We start with nutrition supplements, then medicine to increase appetite, and lastly tube feeding. All the interventions are standard of care during therapy. The research components of this study include the assignment to a nutrition treatment group, the ultrasound measurements, and biomarker (lab) measurements.

Your child will have their diet intake, body muscle and fat changes, and labs taken at different times throughout this study. These time points include at diagnosis and up to three times after assignment to treatment group. If your child keeps their weight at 3 months since starting therapy, they will have these measurements completed at 3 and 6 months of therapy. If they lose more than or equal to 10% from their weight at diagnosis, they will then be assigned by chance (like flipping a coin) to receive one of the three nutrition treatments. These groups assign the participant to either oral nutrition supplements, appetite stimulants, or tube feeding by a tube from the nose into the stomach. In the event of weight loss, you will complete these measures at group assignment, 1 month after assignment, and 3 months after assignment. The assignment process will occur via the Center for Clinical and Translational Science (CCTS) Biostatistics, Epidemiology, & Research Design (BERD) services. There are equal chances to being assigned to one group (33% chance).

- For the body composition, your child will be asked to participate in an ultrasound (US) of the leg to measure the quadricep muscle.
    - US: Your child will be asked to lay on the exam table or hospital bed with their leg propped up. An ultrasound probe will then be placed on the leg to take a picture of the muscle. This will be completed on each side of the leg for a total of 3 pictures per leg. The total measurement times will take approximately 20-30 mins in KCH inpatient room or in the Peds Hem/Onc clinic room.
    - Anthropometric Measurements: To determine your child's weight, height, and body mass index, your child will be asked to provide a few measurements. Standing height and body weight will be measured by a member of the research or clinic nursing team using the correct scale and ruler. This will take approximately 5 minutes in the Peds Hem/Onc clinic.
- Physical Activity Measures: Your child will be asked to provide a self-reported list of their activity level. This measurement will last 5-10 minutes and will take place in the KCH inpatient room or Peds Hem/Onc clinic room.
- Nutritional Assessments: Your child will be asked to provide a 24hr log of their diet intake (including food and drinks). This measurement will last 5-10 minutes. This procedure will take place in the KCH inpatient room or Peds Hem/Onc clinic room.
- Biomarker Determination: Labs are being obtained to see if we can relate muscle status or body composition changes to laboratory findings. Additionally, these could help us trend labs during therapy for response to nutrition treatment. For biomarker measures they will have a small amount of blood taken from the central venous line (6mL, a little more than a teaspoon each time for a total of 18-24mL or 4-5 teaspoons). These samples will be drawn up to 4 times throughout the study. These blood samples will be drawn during regularly scheduled lab draws for clinic needs with the use of numbing cream (EMLA) that numbs the skin prior to having a pediatric hematology/oncology clinic registered nurse access the central line. Central lines (Port-a-caths, aka "ports" or other central lines) will be accessed at each clinic visit for chemotherapy and lab checks. These study labs will be collected at the same time. This procedure will take place in the KCH inpatient room or Peds Hem/Onc clinic room.

In addition to the measurements taken, if your child loses more than or equal to 10% of their diagnosis weight, they will be asked to participate in an assigned nutrition treatment group. The three groups include oral nutrition supplements, appetite stimulants, or tube feeding.

- Oral nutrition supplements (ONS): Those receiving ONS will be prescribed a formula (like Pediasure, Boost, or Ensure) that will meet at least 50% of calorie needs to help with weight gain but allow for regular solid food intake. The flavors come in vanilla, chocolate, and sometimes strawberry. The ONS will be prescribed as 8oz (240mL) per dose at least once a day, but up to six times per day depending on your nutritional needs.
- Appetite stimulants: Those receiving age-appropriate appetite stimulants will be provided either cyproheptadine or olanzapine. Those will be given cyproheptadine if they fall between the ages of 2-12 years of age and olanzapine if they are ≥12 years of age or older. Cyproheptadine will be started at a twice a day dosing and can be adjusted within 2-4 weeks of initiation due to side effects or desired weight gain. Those receiving cyproheptadine (periactin) will receive either a liquid or tablet per your preference. Olanzapine (Zyprexa) will be in tablet or oral disintegrating tablet (ODT) form. Olanzapine will be given as a once a night dose and can be adjusted within 2 weeks of initiation.
- Enteral nutrition/tube feeding (EN): Those assigned to EN will have a feeding tube placed and started on tube feeds by a pump to give feedings overnight, meeting a minimum of 50% of calorie needs to allow for regular food intakes during the day. The placement of a temporary feeding tube will occur by trained professionals on the feeding tube team at the University of Kentucky. Procedures for the placement of a feeding tube include confirmation of patient name and identifiers by the feeding tube team. The receiver of the Cortrak machine is placed on the chest of the patient. The tip of the tube is inserted into their nose and the patient is asked to swallow if they can. The placer is watching the Cortrak machine tracing to ensure adequate placement. Once the tube is ending at the correct location, the placer will flush air through the tube to ensure that it is working. The tube is secured to prevent accidental removal. An x-ray (picture) of the stomach will be taken after placement to make sure the tube is in the right spot. You will be asked to give tube feeding each night while the participant sleeps to provide good nutrition. The length of time and speed of giving the feedings will be determined for each patient by the patient, family, and research dietitian. In addition to giving tube feedings, you will be asked to flush the tube with 10-30mL of water prior to and after giving the feeds. The tube may have to be adjusted or replaced if it becomes clogged or removed at any point during the study.

Participants will complete the study if they regain the weight lost at randomization, complete cancer therapy, or complete ultrasounds and biomarker measurements, whichever comes first.

There will be a total number of 3 research visits which will occur after your standard of care visit. These visits will last approximately 40 minutes in length to collect the ultrasound measurements, physical activity level, and nutritional intake information. The biomarker laboratory collection will happen during laboratory draws for chemotherapy within the first 5-10 minutes of your standard of care visit.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Risks associated with this study are greater than minimal but presenting the prospect of direct benefit to individual subjects. There is a risk of discomfort with the feeding tube placement, side effects from medication, and small radiation exposure due to an x-ray of the stomach to confirm location of feeding tube placement. Additional feeding tube risks include dislodgement or clog requiring replacement, sore throat, nosebleeds, and sinus infection. Considering these risks, the participant will be closely monitored to reduce any risks. The risk of the blood draw procedure includes bruising, bleeding, and infection. However, with careful standardized sterile techniques with qualified and trained pediatric cancer clinic registered nurses, these risks are minimized. There is always a chance that any medical treatment can cause harm. The research treatments/procedures in this study are no different. In addition to risks described in this consent, your child may experience a previously unknown risk or side effect.

The risk of side effects from appetite stimulants (cyproheptadine and olanzapine) are also a possibility.

- Olanzapine (Zyprexa)
  - Common side effects: drowsiness, headache, constipation, fatigue, dizziness, insomnia, and dyspepsia.
  - Uncommon side effects: Falling, urinary incontinence, articulation impairment, hypertension, menstrual disease, muscle rigidity, urinary tract infection, breast changes, and dyskinesia.
- Cyproheptadine (Periactin)

- Common side effects: tiredness, sleepiness, dizziness, hypotension, and dryness of nose/throat.
- Uncommon side effects: nervousness, excitation, tremor, hallucinations, rash, tachycardia, epigastric distress, anorexia, nausea, vomiting, diarrhea, and constipation.

These side effects will be measured using the Common Terminology Criteria for Adverse Events (CTCAEs). Side effects that are labeled a Grade 4, defined as "Life-threatening consequences; urgent intervention indicated", will lead to medical attention and stopping the intervention.

WILL YOUR CHILD BENEFIT FROM TAKING PART IN THIS STUDY?

If assigned to a nutrition treatment group, will receive the benefit of improving nutritional status through one of the three nutrition treatments. Additionally, your child's participation may help provide new information that may be helpful to others going through treatment for pediatric cancer.

IF YOU DON'T WANT YOUR CHILD TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If your child loses weight outside of this study, they will be treated as medically appropriate by the pediatric hematology/oncology team which may include the use of oral nutrition supplements, appetite stimulants, or enteral nutrition via a temporary feeding tube.

WHAT WILL IT COST YOU IF YOUR CHILD PARTICIPATES IN THIS STUDY?

You and/or your child's insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that your child would normally receive for any conditions your child may have. These are costs that are considered medically necessary and will be part of the care your child receives even if your child does not take part in this study.

WHO WILL SEE THE INFORMATION THAT YOUR CHILD GIVES?

When we write about or share the results from the study, we will write about the combined information. We will keep your child's name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that your child gave us information, or what that information is. The data will be entered and verified by approved study personnel weekly. Any 'paper copied documentation' will be stored in a locked file cabinet in the Peds Hem/Onc Clinic. All procedures will be conducted by trained personnel serving as significant personnel of this protocol.

You should know that in some cases we may have to show your child's information to other people. For example, the law may require us to show your child's information to a court or to tell authorities if you report information about a child being abused or if your child poses a danger to themselves or someone else. Finally, officials of the University of Kentucky may look at or copy pertinent portions of records that identify your child.

To ensure the study is conducted properly, officials of the University of Kentucky may look at or copy pertinent portions of records that identify your child. We will make every effort to safeguard your child's data, but as with anything online, we cannot guarantee the security of data obtained by way of the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky. REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your child's data in REDCap.

Researchers will take careful steps to keep the information confidential. We will remove the child's name or other direct identifiers from their information. We will label the child's information with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the code to the children.

Researchers will store the identifiable information or samples, in a locked freezer and password-protected database. Researchers will remove the child's name or other direct identifiers from the child's information or samples. We will label the child's information or samples with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the code to the child. Any remaining information and samples will be destroyed. In addition, it may be possible to destroy the code that links the child's information and specimen samples.

CAN YOUR CHILD CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

Your child can choose to leave the study at any time. Your child will not be treated differently if your child decides to stop taking part in the study.

If your child chooses to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove your child from the study. Your child may be removed from the study if:

- Your child has intolerance to supplements or tube feeding formula (such nausea, vomiting, abdominal cramping, etc),
- Your child has a Grade 4 or greater adverse event (measured by CTCAEs) to appetite stimulants,
- Your child loses an additional 10% of their body weight from randomization.

If your child is removed from study, they will be provided with immediate appropriate medical care based on clinical status.

IS YOUR CHILD PARTICIPATING, OR CAN YOUR CHILD PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

Your child may take part in this study if your child is currently involved in another research study. It is important to let the investigator/your doctor know if your child is in another research study. You should discuss this with the investigator/your child's doctor before you agree to allow your child to participate in another research study while he/she is in this study.

WHAT HAPPENS IF YOUR CHILD GETS HURT OR SICK DURING THE STUDY?

If you believe your child is hurt or if they get sick because of something that is due to the study, you should call Amanda Harrington MD (859-257-4554) or Corey Hawes Doctor of Clinical Nutrition (859-323-7230) immediately.

They will determine what type of treatment, if any, is best for your child at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because your child gets hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you or your child may lose if your child is harmed by this study.

Medical costs related to your child's care and treatment because of study-related harm may be paid by your child's insurer if he/she is insured by a health insurance company (you should ask your child's insurer if you have any questions regarding your child's insurer's willingness to pay under these circumstances)

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your child's insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly.

You do not give up your child's legal rights by signing this form.

WILL YOUR CHILD RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

Your child will receive a $40 gift card **if assigned to a nutrition treatment group** for taking part in this study.

With a few exceptions, study payments are considered taxable income reportable to the Internal Revenue Service (IRS). A form 1099 will be sent to you if your child's total payments for research participation are $600 or more in a calendar year.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO ALLOW YOUR CHILD TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about having your child remain in the study. We may ask you to sign a new consent form if the information is provided to you after your child has joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FOR YOUR CHILD FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. We will provide you with your child's individual research results.

There is a slight possibility that during a research project, an investigator could discover something that could affect the health of your child or your family. If this occurs, the finding will be reviewed by an expert consultant to determine if it is in your child's best interest to contact you.

If so, your child's medical provider will contact you using the information your child provided. With the help of a medical specialist, they will present possible risks or benefits of receiving the information. At that time, you can choose to receive or refuse the result or finding. If you would like more information about this, call Corey Hawes Doctor of Clinical Nutrition.

You may also withdraw your consent to be contacted with information about your child's research results or incidental findings by sending a written request to Corey Hawes, Kentucky Children's Hospital, 800 Rose street, C428, Lexington, KY 40536-0298

WHAT ELSE DO YOU NEED TO KNOW?

If you give permission and your child decides to volunteer to take part in this study, your child will be one of about 45 people to do so.

Corey Hawes Doctor of Clinical Nutrition is the pediatric cancer dietitian with the pediatric hematology/oncology team. Amanda Harrington MD is a pediatric cancer doctor that is also with the pediatric hematology/oncology team. Kelly Zavitz PharmD, BCPPS is a pediatric cancer pharmacist that is also with the pediatric hematology/oncology team. There may be other people on the research team assisting at different times during the study.

STORING AND SHARING YOUR CHILD'S INFORMATION OR SPECIMEN SAMPLES FOR FUTURE USE:

If there are leftover blood samples, the researchers would like to store, use, and share your child's blood samples for future research. Researchers can use the stored blood samples to learn more about pediatric cancer and obesity, or pediatric cancer and nutrition. Information including diagnosis, age, and treatment protocol will be kept with leftover blood samples if there are any.

Researchers would like to have permission to look at your child's medical records from time to time. Researchers would collect general information related to your child's health such as test results, treatments, and doctor's notes. The confidentiality section below provides details about how we will keep your child's information private.

WHERE WILL INFORMATION OR SPECIMEN SAMPLES BE STORED AND FOR HOW LONG?

The information will be stored at the Center for Clinical and Translational Studies (CCTS), in a -80 freezer indefinitely.

ARE THERE RISKS FROM ALLOWING YOUR CHILD'S INFORMATION OR SPECIMEN SAMPLES TO BE STORED FOR FUTURE RESEARCH?

There is a risk that someone could get access to the stored information or samples. In spite of the security measures and safeguards we will use, we cannot guarantee that your child's identity will never become known.

Even without your child's name or identifiers, genetic information is unique to you. The results of genetic research apply to both your child and your family members. Genetic information used improperly to discriminate or support negative stereotypes could cause your child or your family distress. We do not know whether future technology will make it possible for someone to trace your child's genetic information back to him/her.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). Generally, GINA makes it illegal for health insurance companies, group health plans, and most employers to discriminate against your child based on your child's genetic information. Be aware that GINA does not protect your child against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of an already known genetic disease.

HOW WILL YOUR CHILD'S PRIVACY AND CONFIDENTIALITY BE PROTECTED?

We will take careful steps to keep your child's information confidential. We will remove your child's name or other direct identifiers from their information. We will label your child's information with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the code to your child.

Researchers will store your identifiable information or samples, in a locked freezer and password-protected database. Researchers will remove your child's name or other direct identifiers from your child's information or samples. We will label your child's information or samples with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the code to your child.

HOW WILL WE SHARE YOUR CHILD'S INFORMATION OR SPECIMEN SAMPLES WITH OTHER RESEARCHERS?

Your child's de-identified information or samples may be shared with other researchers without your additional informed consent, provided an Institutional Review Board (IRB) has approved this action. An IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human participants. If a researcher requests your child's information or samples with identifiable information, an IRB will decide if the research may be conducted with or without your additional consent.

The researchers requesting access to your child's information must complete an application process and sign an agreement. The researchers who receive your child's information will sign an agreement to use the data responsibly.

WHAT IF YOU CHANGE YOUR MIND AND WANT TO WITHDRAW YOUR CHILD'S INFORMATION OR SPECIMEN SAMPLES?

You may withdraw your permission to allow your child's information or samples to be used for future research. To do so, you must send a written withdraw request to Corey Hawes Doctor of Clinical Nutrition at DanceBlue Hematology & Oncology Clinic, 800 Rose Street Suite C428, Lexington KY 40536-0298

Any remaining information and samples will be destroyed. In addition, it may be possible to destroy the code that links you with your child's information and specimen samples. However, the information and samples that have already been used or shared may not be withdrawn.

WILL YOU OR YOUR CHILD RECEIVE ANY COMMERCIAL PROFIT FROM FUTURE RESEARCH DISCOVERIES?

The information and samples that your child provides will no longer belong to you or him/her. The research may lead to new medical knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you, your child or your relatives should this occur.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE FUTURE RESEARCH TESTS?

Tests done for research purposes are not meant to provide clinical information or help care for your child. The results are only important for research. Therefore, the results of tests done with your child's information and samples will not be provided to you. In the rare event that a finding might affect the health of your child or your family, we will contact you and you can choose whether to receive or refuse the information.

OPTIONAL FUTURE USE:

Do you give permission for your child's identifiable information and blood specimens to be stored, used, and shared for future research? ☐ Yes ☐ No Initials _____

Remember, your child can still be in the main study even if you do not wish to allow your child's information and/or specimens stored or shared for future research.

AUTHORIZATION TO USE OR DISCLOSE YOUR CHILD'S IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your child's health information. The following sections of the form describe how researchers may use your child's health information.

Your child's health information that may be accessed, used and/or released includes:

- Demographic data, cancer diagnosis, anthropometrics, body composition results, results from blood tests, physical activity information, nutritional intakes and psychosocial information, and other diagnostic and medical procedures, as well as medical history.

The Researchers may use and share your child's health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- UK HealthCare and their representatives
- Health systems outside of UK for which you have a patient relationship;
- Center for Clinical and Translational Science (CCTS)
- National Cancer Institute (NCI)
- The primary pediatric oncologist will be contacted if the researcher, in the course of the project, learns of a medical condition that needs immediate attention.

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information may still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky;
- Current or future payments to the University of Kentucky;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable)

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your child's health information (revoke the Authorization). If you revoke the authorization:

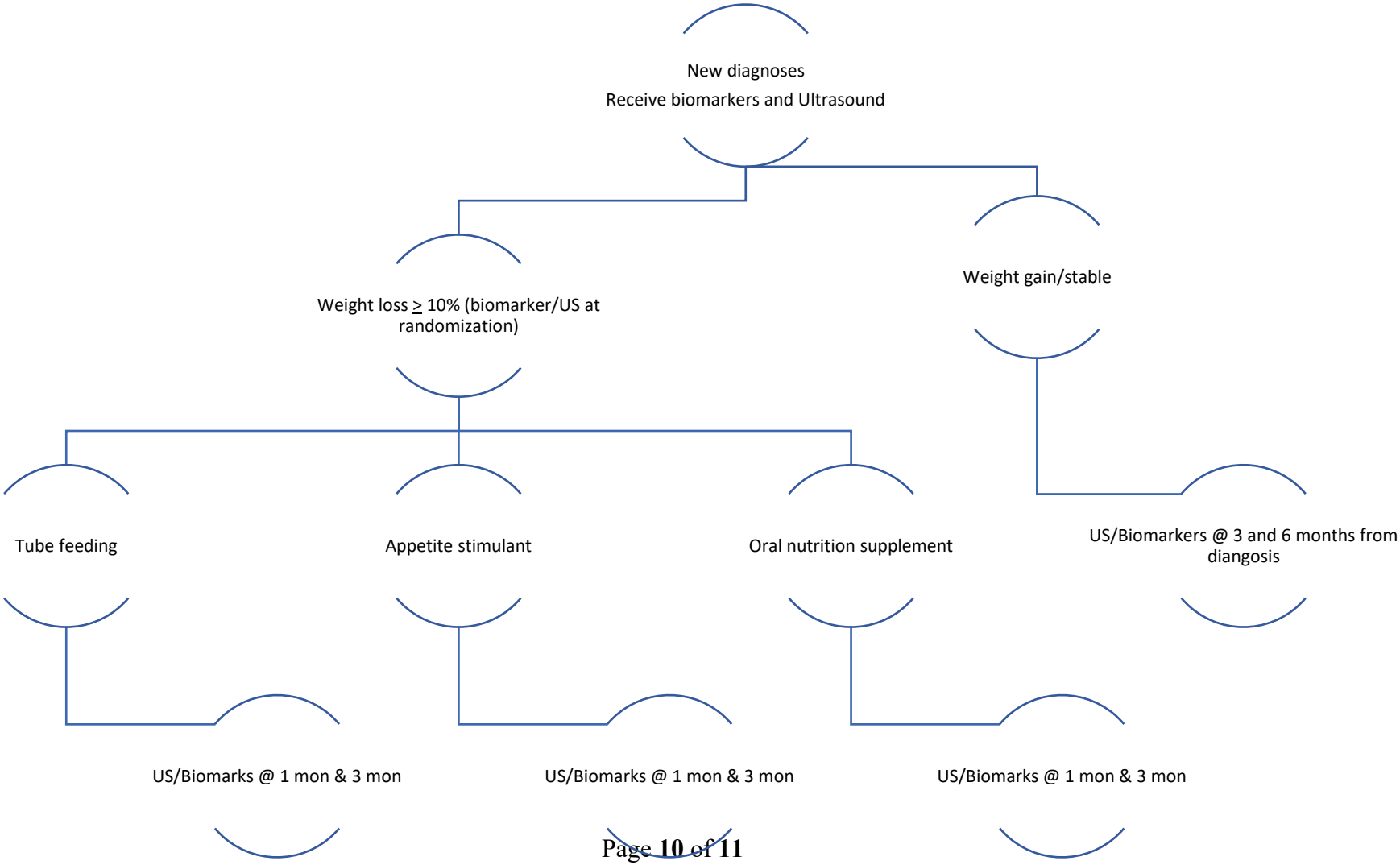
- Send a written letter to: Corey Hawes Doctor of Clinical Nutrition at DanceBlue Hematology & Oncology Clinic, 800 Rose Street Suite C428, Lexington KY 40536-0298 to inform him of your decision.
- Researchers may use and release your child's health information **already** collected for this research study.
- Your child's protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your child's information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your child's privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

Appendix: Study Procedures and Assignment

Example of Randomization tree/procedure timing:



INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**
- **Appendix I: Study Procedures and Randomization**

You will receive a copy of this consent form after it has been signed.

_____ **Signature of research subject** *or, if applicable, parent or guardian*	_____ **Date**
_____ **Printed name of research subject** *or, if applicable, parent or guardian*	
_____ **Signature of Legally Authorized Representative**	_____ **Date**
_____ **Printed name of research subject's legal representative*	
**If applicable, please explain Representative's relationship to subject and include a description of representative's authority to act on behalf of subject:* _____ _____	
_____ Printed name of [authorized] person obtaining informed consent and HIPAA authorization	
_____ Signature of [authorized] person obtaining informed consent and HIPAA authorization	_____ Date