A: TITLE: Comparison of a locally produced, alternative therapeutic food to a standard ready-to-use therapeutic food (RUTF) for the treatment of severe acute malnutrition in children from the Brong Ahafo region of Ghana.

B: INVESTIGATORS: Dr. Mark Manary, MD; Prof. F.K. Saalia; Prof. Matilda Steiner-Asiedu; Jacklyn Weber, BS; Meghan Callaghan, MPH

C: INSTITUTIONS:

Nutrition and Food Science Dept., University of Ghana, Accra Ghana
Patient Oriented Research Unit, Washington University School of Medicine, MO USA

D: EXECUTIVE SUMMARY

Type of study: A randomized controlled double-blinded clinical equivalency trial.

Problem to be studied: Severe acute malnutrition (SAM) is the cause of 10% of deaths worldwide. Ready-to-use-therapeutic food (RUTF) is a micronutrient-fortified peanut butter paste that has been highly successful in the treatment of SAM. An alternative RUTF formulation that is nutritionally equivalent to standard RUTF, but with a lower associated cost may increase access to treatment.

Objective: To test the equivalency of an alternative RUTF compared to standard RUTF, in the treatment of SAM in 6-59 month old children, in a 12-week home-based feeding program.

E. BACKGROUND INFORMATION AND INTRODUCTION

Worldwide, 10% of deaths among children under five years of age are caused by severe acute malnutrition (SAM) [1]. Children with SAM, defined as a weight-for-height Z-score (WHZ) less than -3, experience an increased number of infectious diseases, delayed cognitive development, and decreased adult stature and productivity. The current World Health Organization recommended treatment for children suffering from SAM is ready-to-use therapeutic food (RUTF),a highly successful micronutrient-fortified, high lipid (45-60% total energy), high protein (10-12% total energy) and overall high energy food (520—550 kcal/100 g).[2] Since 2007, the United Nations agencies have recommended home-based therapy with ready-to-use therapeutic food (RUTF) for the treatment of uncomplicated SAM. Low moisture, ready-to-eat foods are not conducive to the growth of bacteria, do not require cooking, and have led to greater recovery rates than other forms of treatment for SAM.

In Ghana 4.74% of children under five are undernourished and 0.74% of those are severely malnourished [3]. This study will utilize an alternative therapeutic food made from locally procured ingredients and will be produced at Project Peanut Butter in Kumasi.

In this prospective, double-blinded, randomised controlled clinical equivalency trial, two foods will be compared for the treatment of SAM, testing the hypothesis that the difference in recovery rates between the two test groups will be no greater than 5 percent.

F. RATIONALE/JUSTIFICATION: Children with SAM may benefit from an alternative therapeutic food that is nutritionally equivalent to standard RUTF. The overall cost associated with an alternative RUTF can be 20-30% less than standard RUTF potentially resulting in a more cost effective treatment.[4] Cost saving calculated using a linear programming tool can be a practical way to show the cost savings of introducing novel local ingredients and milk powders with concentrated forms of protein. [4, 5] A clinical trial showing the equivalency in recovery from SAM is the proper method by which to test this hypothesis.

G. OBJECTIVES:

Broad: To provide government and international agencies with an alternative to the standard treatment for SAM.

Specific: To test the equivalency of an alternative RUTF compared to standard RUTF, in the treatment of SAM in 6-59 month old children, in a 12-week home-based feeding program.

The specific outcomes are:

a. Mid-upper-arm circumference
b. Weight-for-height z score

Secondary outcomes:

a. Adverse symptoms, such as stomach pain, vomiting, diarrhea, rash or fever.

H. METHODOLOGY

Type of research study: This will be a randomised, double-blinded, controlled clinical equivalency trial assessing the treatment of SAM with one of two therapeutic foods until the child is recovered or for a period of up to 12 weeks.

Study place: Subjects will be recruited from rural health clinics in the Brong Ahafo Region of Ghana, due to the limited accessibility of treatment programs in this area; investigators believe a clinical trial in this region will be beneficial.

Study population: Ghanaian children aged 6-59 months with uncomplicated SAM (with WHZ < -3, MUAC of <11.5 cm, or bipedal edema without renal disease or severe anemia) will be recruited at health clinics in Brong Ahafo Region**.** A total of 1,800 children will be enrolled, to detect a 5% difference in recovery rates between any two foods, with 95% sensitivity and 80% power, assuming that the standard recovery rate is 85% and using a 1-sided difference of equivalence (Fisher's exact test).

Study period: After screening and enrolment, each child's participation will last up to 12 weeks. If a child recovers before the end of the 12-week period, a child's WHZ reaches and stays above -2 and his or her MUAC remains greater or equal to 12.5 for two consecutive visits without edema, the child will graduate from the study. No study food products will be given to children after 12 weeks of participation; those who have not recovered will be taken for inpatient treatment. Children will enter the study on a rolling enrolment basis and will continue to be enrolled until 1,800 children complete the study.

Randomization will be blocked for the entire study rather than at each study site. Allocation of food intervention will be conducted by nurses who will have the caregiver draw opaque envelopes containing one of 4 colors. Caretakers chose a sealed envelope that contains 1 of 4 colors: 2 of these colors correspond to the control food and 2 to the experimental food. The color will be recorded separately from the child's clinical measurements and researchers involved in the randomization process do not know which color corresponds to which food corresponding to one of the therapeutic foods. The code will be accessible only to the food distribution personnel, who do not assess participant outcomes or eligibility. Investigators performing clinical assessments and caretakers will be blinded to the child's assigned food group.

Year	1	2	3
Alternative RUTF Development, IRB approval, site selection and staff training			
Participant Recruitment and enrollment			
Participant follow-up and data collection			
Data analysis			

Inclusion/exclusion criteria:

Inclusion criteria: Children aged 6-59 months with WHZ < -3, MUAC <11.5 cm, or bipedal edema without renal disease or severe anemia.

Exclusion Criteria: Exclusion criteria include children currently involved in another research trial or feeding program, are developmentally delayed, have a chronic debilitating illness (such as cerebral palsy), or a history of peanut or milk allergy. Children will also be excluded if they experience serious adverse effects to the study food (such as an allergic reaction), or had received therapy for acute malnutrition within one month prior to presentation.

Intervention: The randomized therapeutic food sufficient for two weeks' feeding will be given to the enrolled subject's caretaker with instructions on daily feeding methods and advised not to share the food product with other members of the household. Subjects and caretakers will return for follow-up, food collection, measurements, and monitoring of the child's growth and any adverse events every two weeks until recovery (WHZ ≥ -2 and MUAC≥ 12.5 by 12 weeks) or failure (death, transfer to hospital for inpatient care, remaining malnourished at 12 weeks, default).

Blinding: The RUTF food products are very similar in appearance and texture; thus subjects and caretakers will be blinded. The investigators making the clinical assessments will not have information on the subject's food product assignment, and will remain blinded.

Subject Participation and Data Collection:
Children presenting to each clinic site will be evaluated for severe acute malnutrition by trained researchers. The following measurements will be collected at each visit: weight measured using an electronic scale to the nearest 5 g length measured to the nearest 0.2 cm using a rigid length board; and MUAC measured with a standard insertion tape to the nearest 0.1 cm. Children will also be evaluated for kwashiorkor by assessing for bilateral pitting edema. A height for weight z-score will be calculated by the researcher making clinical assessments. The caregivers of children who meet enrolment criteria will be asked to give verbal and written consent prior to randomization. Children who are enrolled in the study will receive any necessary medicine and medical attention relevant to the study for the duration of the clinical trial.

Upon enrolment, caregivers will sign a consent form [Appendix 1], be interviewed regarding the child's demographic characteristics, appetite, infectious symptoms, gross motor development, and antibiotic usage during the prior two weeks. [Appendix 2]

A ration of therapeutic food sufficient for two weeks' feeding based on the subject's weight will be distributed at each visit, Table 3. Children will be asked to return every two weeks for follow-up, where caretakers report on the child's clinical symptoms, anthropometric measurements are re-assessed, and additional therapeutic food is distributed for those that remained wasted. Adverse effects associated with the study will be recorded; the effected children will be accessed by the research staff and further action will be taken if deemed appropriate. After the investigator becomes aware of any serious adverse events, they will be reported within the following timeframes: to Noguchi IRB, to Washington University IRB within 10 working days of the occurrence of the event or notification to the PI or research team of the event, to Ghana Health Service Ethical Review Committee within 72 hours, and the Food and Drugs Administration within 48 hours. Children enrolled in the study who miss a biweekly visit will be sought out by village health workers at their homes to encourage attendance at the next biweekly appointment. Children that miss 3 consecutive biweekly visits will be considered lost to follow up and a default within the study.

No additional food rations will be distributed when subjects reach an outcome: recovery (MUAC$\geq$ 12.5, WHZ$\geq$-2), death, transfer to hospital for inpatient care, failure to recover by 12 weeks, or default.

Monitoring and Evaluation:

This study will be conducted in compliance with the protocol approved by the Institutional Review Board at Noguchi Memorial Institute for Medical Research, Washington University School of Medicine, and the Ghana Health Services Ethics Review Committee, and according to Good Clinical Practice standards. No deviation from the protocol will be implemented without the prior review and approval of the IRB except where it may be necessary to eliminate an immediate hazard to a research subject. In such case, the deviation will be reported to the IRB as soon as possible. Investigators and study team will be trained in GCP and refresher courses will also be given. A clinical research coordinator from Washington University School of Medicine will be present at feeding clinics to supervise and ensure the conduct of the clinical and to ensure that data are generated, documented and reported in compliance with this protocol, GCP, and the other applicable regulatory requirements laid out by Institutional Review Board at Noguchi Memorial Institute for Medical Research, Washington University School of Medicine, and the Ghana Health Services Ethics Review Committee.

Investigators understand that trial-relating monitoring may be necessary and will permit trial-related monitoring, audits, IRB review and regulatory inspection by providing direct access to source data/documentation.

Food Product:

Participants will receive approximately 190 kcal/kg/day of alternative or standard RUTF. The nutrient content of these foods is listed in **Table 1**. Nurses will instruct caregivers to feed the therapeutic foods to the child consistently for the duration of the study, maintaining proper proportions to last until the next biweekly distribution and to re-emphasize the importance of feeding the food only to the enrolled child, dosing chart shown in **Table 2**. Although the food is a complete diet, the child should not be denied traditional meals.

Children will be fed a test dose of the assigned therapeutic food product at the health center to determine if they will have an acute allergic reaction and the acceptability of the RUTF. To complete the test, children will be given a sachet of RUTF and the child should eat at least one third of the packet within 30 minutes. If the child passes the test, he or she can continue treatment on an outpatient basis. If the child fails the test, referral procedures to inpatient care will be initiated. Caretakers will be instructed to report all rashes to the local health workers, and to return to the health clinic for examination if a rash develops.

The standard and alternative RUTF will be produced by Project Peanut Butter in Kumasi, Ghana. **Table 3** shows the proportion of ingredients used in each formulation. Traditional RUTF contains peanut paste, sugar, non-fat dried milk (NFDM), vegetable oil, a premix containing concentrated minerals and vitamins, and emulsifier. Whereas the alternative RUTF contains oat, sorghum, peanuts, sugar, milk powder, vegetable oil as well as premix and emulsifier. The two locally produced products will undergo quality assurance and food safety testing for aflatoxin and microbial contamination at Eurofins Scientific Inc., Des Moines, Iowa, USA.

Table 1. Nutrient composition of alterative RUTF formulations based on the World Health Organization's nutrient specifications and requirements (2007)

Nutrient Composition	*Requirement*
Moisture content	2.5% maximum
Water activity	0.6% maximum
Energy (kcal)	520-550
Protein	10-12% total energy 13-16% by weight
Lipids	45-60% total energy 26.8-36.3% by weight
n-6 fatty acids	3-10% total energy
n-3 fatty acids	0.3-2.5% total energy
Trans-fatty acids	<3% total fat
Carbohydrate content	41-58% by weight
Fiber	<5%
Ash	3-4% by weight
Vitamins and Minerals	***Requirement***
Minerals (per 100g)	
Sodium (mg)	<290
Potassium (mg)	1100-1400
Calcium (mg)	300-600
Phosphorus (mg)	300-600
Magnesium (mg)	80-140
Iron (mg)	10-14
Zinc (mg)	11-14
Copper (mg)	1.4-1.8
Selenium (μg)	20-40
Iodine (μg)	70-140
Vitamins (per 100g)	
Vitamin A (μg)	0.8-1.2
Vitamin D (μg)	15-20
Vitamin E (mg)	>20
Vitamin K (μg)	15-30
Vitamin B1 (mg)	>0.5
Vitamin B2 (mg)	>1.6
Vitamin C (mg)	>50
Vitamin B6 (mg)	>0.6
Vitamin B12 (μg)	>1.6
Vitamin B9 (μg)	>200
Vitamin B3 (mg)	>5
Vitamin B5 (mg)	>3
Vitamin B7 (μg)	>60

Table 2. RUTF distribution chart for severe malnutrition (exclusive feeding).

Weight	Sachets of RUTF for 2 weeks
4 kg	20
4.5 kg	22
5 kg	25
5.5 kg	27
6 kg	30
6.5 kg	32
7 kg	35
7.5 kg	37
8 kg	39
8.5 kg	42
9 kg	44
9.5 kg	47
10 kg	49
10.5 kg	52
11 kg	54
11.5 kg	57
12 kg	59
12.5 kg	62
13 kg	64
13.5 kg	66
14 kg	69
14.5 kg	71
15 kg	74

Table 3. Weight (g) of the alternative Ghana formula and the current ready-to-use therapeutic food (RUTF) formula.

Ingredients List	Alternative RUTF Ghana 48	Standard RUTF Project Peanut Butter
Soybean (cooked, processed into flour)	2.00	-
Sorghum (cooked, processed into flour)	8.00	-
Groundnut (dry roasted, without skin)	16.00	26.00
Oil, Canola, Rapeseed	13.32	-
Oil, Coconut	-	-
Oil, Palm	-	15.50
Oil, Soybean	10.0	2.9
Sugar, White	22.00	25.64
Milk, Nonfat dried	3.45	25.00
Milk, Whey protein concentrate 34	21.23	-
Nutrient Premix/Emulsifier	4.00	4.96
TOTALS	100.00	100.00

Data Management/Analysis:
This trial will be registered with ClinicalTrials.gov.

All data will be double entered, checked, sealed and analyzed in an electronic database before the randomization code is broken. Data will be entered into a Microsoft® Access database and exported to Microsoft® Excel and SPSS (Version 23.0, IBM Somers, NY) for analysis.

Children will be defined as having recovered when they reach WHZ $\geq$ -2 and MUAC$\geq$ 12.5 ; otherwise they will be categorized as having remained malnourished, being transferred to inpatient care, dying, or defaulting (did not return for three consecutive visits). Secondary outcomes include the rates of gain in weight, length, and MUAC, time to recover, and development of adverse events from either food. If the child is a twin, an additional supply of food will be given to the caretaker to ensure that the child receives a full ration and to limit sharing between the twins. If there are two study participants in the same household, both children will be given the same type of food to reduce the likelihood of confounding study foods.

Weight gain in g/kg/d, relative to the enrolment weight is calculated for graduates over the first four weeks (or less if they graduated earlier) of enrolment. Anthropometric indices are calculated using WHO 2006 standards. Length and MUAC gain, in mm/d, are calculated over the entire duration of study participation. Baseline characteristics will be tabulated as means $\pm$ SD for continuous variables, and as n (%) for dichotomous measures. Comparisons of outcomes between types of therapeutic foods will be made using Fisher's Exact test for dichotomous parameters, and Student's t-test for continuous parameters. The logrank test will be used to compare the graduation rates over time between the two foods. P-values less than 0.05 will be considered to be statistically significant. Intention-to-treat analysis will be used.

Binary logistic regression will be used to identify risk factors for failure (IBM SPSS Statistics 23.0, Somers NY). The dependent variable will be failure to recover; independent covariates will be sex, enrolment MUAC, number of days of fever, vomiting, cough, and diarrhea within the two weeks prior to enrolment, current treatment with antibiotics, whether the mother is the primary caregiver, season of enrolment, and the ability to stand alone.

Results Presentation: Results of all primary and secondary outcomes will be presented in tables. Any statistically significant relationships will be presented in line graphs or histograms as appropriate.

Dissemination of the results: A report of all results will be submitted to the supporting institutions Children's Investment Fund Foundation (CIFF), University of Ghana, Project Peanut Butter and Washington University School of Medicine as well as to the participating patients that wish to receive the results. The results will further be submitted to a peer-reviewed journal for publication.

I. ETHICAL CONSIDERATIONS

The study has been structured in accordance with the International recommendations guiding doctors in biomedical research involving human participants, and will be approved by the University of Ghana Food Ethics Review Board, Food and Drug Administration, and Institutional Review Board of Washington University. Additionally, on the day of enrollment for each phase, participants will be informed about the duration and requirements of participation in the study, and the benefits of participation in the study, through an interactive oral presentation as well as through consent forms. Only participants who express continued interest in the study after being fully informed will be enrolled. The informed consent in English will be explained to participants in local language if they cannot read the English language (Appendix 1).

Respect for autonomy: Caretakers will be repeatedly told that participation is voluntary, and that they can quit at any time without consequences.

Compensation for participation: Upon completing the enrollment testing, and at the conclusion of the study, each study participate will receive a token of appreciation; a bar of soap, a plastic pail, and/or a half piece of cloth (6 yards).

J. UNEXPECTED EVENTS

Any unexpected events will be handled by the on-site investigators, FK Saalia or Matilda Steiner. In all cases of unexpected events, the study team will report the event to Mark Manary or Jacklyn Weber immediately.. In the case of severe adverse events, unblinding of the study participants may be necessary to facilitate clinical care. The nurse on-site will hold the unblinded allocations and codes which will be accessed in the case of a life-threatening adverse event, the need for inpatient hospitalization, or other significant incapacitation of the study participant.

In the rare case of allergy or anaphylactic reaction to the study food, the staff will immediately treat the patient, and take him/her to the local health center if needed Caretakers will be instructed to report all rashes and other adverse events to the local health workers, to discontinue taking the medication, and to return to clinic for examination if adverse events develop. In treating thousands of children in local feeding clinics, the PI and his team have seen rashes only a few times, never anaphylaxis; adverse food reactions are incredibly unlikely. For more information about the PI's clinical trials visit:

https://clinicaltrials.gov/ct2/results?term=Mark+Manary. Children who experience these adverse outcomes will be removed from our study.

All unexpected events will be reported to the field director and PI with the utmost urgency and care for the patients. If the investigator becomes aware of any serious adverse events, they will be reported within the following timeframes: to Noguchi IRB within ***, to Washington University IRB within 10 working days of the occurrence of the event or notification to the PI or research team of the event, to Ghana Health Service Ethical Review Committee within 72 hours, and the Food and Drugs Administration within 48 hours

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APPENDIX 1

CAREGIVER CONSENT

Project Title: Comparison of a locally produced, alternative therapeutic food to a standard ready-to-use therapeutic food (RUTF) for the treatment of severe acute malnutrition in children from the Brong Ahafo region of Ghana.

Principal Investigator: Prof. Mark Manary and Prof. F.K Saalia

Address: PO Box 134, Department of Nutrition and Food Science, University of Ghana, Legon, Accra

GENERAL INFORMATION ABOUT RESEARCH

1. The purpose of this study is to improve the treatment of severe acute malnutrition in the Brong Ahafo region of Ghana using a cost effective alternative RUTF product that is nutritionally equivalent to the standard RUTF. The cost associated with the alternative RUTF production is at least 30% less than the standard RUTF resulting in a more cost effective treatment for children with severe acute malnutrition.
2.

An integral part of the therapeutic food development process is equivalency trial, a scientific study to compare the two different treatments for severe acute malnutrition and to show that they have similar outcomes in regards to how your child will recover This research will compare recovery rates, growth and weight gain using one of two RUTF products to improve the treatment of other children with severe acute malnutrition.

3. Ingredients contained in the study foods are oats, groundnuts, sorghum, milk powder, canola oil, palm oil, soybean oil, coconut oil, and sugar. These ingredients are commonly consumed entails minimal risks. An emulsifier and a micronutrient premix, both already used in RUTF in Africa, will also be added for stability and to assure the proper micronutrient nutrition, respectively. The vitamins and minerals important for healthy growth and development are contained in each of the supplements. The type of food your child receives is determined by the study.

4. Children and caretakers will gather at the identified location every two weeks in the morning, during which instruction will be given, food distributed, measurements taken and questionnaires administered.

5. At the beginning of the study you will be asked questions about dietary intake and demographics of your child. Additionally, the child's appetite, illness symptoms and sign, rash and growth pattern will be recorded before providing the food supplements

6. After selection, your child will get the food supplements to take home. You will be given enough food to feed the child for 2 weeks, and asked to return every 2 weeks to be weighed, measured and given more food if the child is still malnourished. The caretaker will be asked to feed the child this food until noted by the research team. You will also be asked information regarding quantity of study food intake by your child, symptoms and any sharing that occurred. The same questionnaires will be administered every 2 weeks over the course of the study.

7. Your (your child's) participation is expected to last 8-12 weeks of therapy with follow-up visits up to 3 months after completion of therapy.

8. There is no cost to the participants. The research project will provide all foods and tests.

9. If you agree to participation of your own or custody child, the child will be assigned to the study group of the test site. The investigators will interview you and provide the RUTF for the child as described below.

POSSIBLE RISKS

There are certain risks and discomforts such as stomachache and loose stools that may be associated with this research; rarely your child may develop an allergy to the supplement. If this occurs, the food supplement will be stopped and treatment will be given, paid for by the research team.

Participation in this study may cause all or some of the side effects listed above, which may be serious or even life threatening. In addition, there is always the risk of developing previously unknown side effects.

The investigator is willing to discuss any questions you might have about these risks and discomforts.

POSSIBLE BENEFITS

Your child will be given a balanced food supplement that contains all of the nutrients that is necessary for recovering from severe acute malnutrition. Doctors will use the information they collect to understand how to formulate therapeutic food products. However, there are no other specific benefits to your child.

CONFIDENTIALILTY

All reasonable measures to protect the confidentiality of your child's records and your child's identity will be taken. There is a possibility that your child's medical record, including identifying information, may be inspected and photocopied by government, University or Human Studies Committee officials. But your child will not be named in any reports.

COMPENSATION

At the conclusion of the study, you and your child will be given a token of appreciation. This may include a bar of soap, a pail, and or a piece of clothing.

VOLUNTARY PARTICIPATION, Right to Leave the Research

This study is voluntary and you may withdraw your participation at any time. Please inform the research staff at the next clinic visit that you would no longer care to participate.

You (your child) will be informed of any significant new findings developed during the course of participation in this research that may have a bearing on your (your child's) willingness to continue in the study. The investigator may withdraw you (your child) from this research if circumstances arise (such as non-compliance with the protocol and non-tolerance of a study medication) which warrant doing so. This research is not intended for the purpose of diagnosing or treating any medical problems not specifically stated in the purpose of the research.

CONTACT AND ADDITIONAL INFORMATION
If you have any questions or concerns regarding this study, if any problems arise, or you are feeling pressured to participate, please contact the principal investigator Dr. Mark Manary, Jacklyn Weber, Dr. Matilda Steiner or Dr. F.K Saalia at the University of Ghana, Department of Nutrition and Food Science.

The University of Ghana and Washington University School of Medicine investigators and their staff will try to reduce, control, and treat any complications from this research. If you feel that you are injured because of the study, please contact the Investigator and/or the Human Studies Committee Chairman.

YOUR CHILD'S RIGHTS AS A PARTICIPANT
This research has been reviewed and approved by the Noguchi Memorial Institute for Medical Research Institutional Review Board (NMIMR-IRB) and the Ghana Health Service Ethical Review Committee. If you have any questions about your child's rights as a research participant you can contact the IRB Office between the hours of 8am-5pm through the landline **0302916438** or email addresses: nirb@noguchi.mimcom.org . You may also contact the Ghana Health Service Ethical Review Committee at [phone number] at all times.

VOLUNTEER AGREEMENT

The above document describing the benefits, risks and procedures for the research titled "Comparison of a locally produced, novel alternative therapeutic food to a standard ready-to-use therapeutic food (RUTF) for the treatment of severe acute malnutrition in children from the Brong Ahafo region of Ghana" has been read and explained to me. I have been given an opportunity to have any questions about the research answered to my satisfaction. I agree that my child should participate as a volunteer.

_____ _____
Date Name and signature or mark of parent or guardian

If volunteers cannot read the form themselves, a witness must sign here:
I was present while the benefits, risks and procedures were read to the child's parent or guardian. All questions were answered and the child's parent has agreed that his or her child should take part in the research.

_____ _____
Date Name and signature of witness

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

_____	_____
Date	Name Signature of Person Who Obtained Consent

APPENDIX 2

Enrollment form

2016 Ghana Alterative RUTF **STUDY ID_____**

Demographics Form

CHILD'S NAME _____ **MALE / FEMALE**

DATE OF BIRTH _____ /_____/_____

dd mm yy

Social, Economic and Demographic Information

1. Name of the guardian/guardian's name:_____
2. How old is the caretaker? /What year was the caregiver born? _____
3. Relationship of the guardian to the child: Mother / Father/ Sister / Aunt / Grandmother / Other_____
4. Is the child's mother alive? Yes/No
   If no go to question 4.
   a. If yes → How many days in the past month did the child not sleep with the mother?
      Never / 1-5 / 6-10 / 11-15 / 16-20 / 21-25 / 26-30 / All days
   b. If yes → In the past month, how many days was the child fed by another person other than the mother?
      Never / 1-5 / 6-10 / 11-15 / 16-20 / 21-25 / 26-30 / All days
   c. If yes → In the past month, how many days was the child cared for by another person other than the mother?
      Never / 1-5 / 6-10 / 11-15 / 16-20 / 21-25 / 26-30 / All days
5. Is the father alive? Yes/No
   a. If yes → does the father stay together with the study child? Yes/No
6. How far did the mother go with education? _____
7. Does the mother know how to read?
   I don't know how to read / at least (she knows, but not much; a little) / I do know how to read / I know how to read almost all / don't know
8. Does the mother know how to write?
   I don't know how to write / at least (she knows, but not much; a little) / I do know how to write / I know how to write almost all / Don't know
9. How far did the father go with education?_____
10. Does the father know how to read?
    He doesn't know how to read / at least (he knows, but not much; a little) / He does know how to read / He knows how to read almost all / Don't know
11. Does the father know how to write?
    He doesn't know how to write / at least (he knows, but not much; a little) / He does know how to write / He knows how to write almost all / Don't know
12. How many siblings does the participant have? 1/2/3/4/5/6/more than this
13. How many siblings have died? 1/2/3/4/5/6/more than this

Income Indicators

14. How many people share the bedroom with the child? 1/2/3/4/5/6/more than this
15. What is the roofing material of the house? Grass or iron sheets?
16. How many radios do you have? 0/1/2/3/more than this
17. How many bicycles do you have? 0/1/2/3/more than this
18. Is the livestock kept in the house where the child sleeps? Yes/No

a. If yes → What type of livestock is kept in the house? Chicken / Dog / Goat / Pig / Guinea Fowl / Other_____

19. What type of crops do you grow?_____
20. What type of commercial crops do you grow/what crops to you grow to sell?
_____
21. What type of crops do you keep for consumption?
_____
22. Does your house have electricity? Yes/No
23. Does the father do anything for a job besides farming? Yes/No/NA
    a. If yes → What type of job?_____
24. Does the mother do anything for a job besides farming? Yes/No/NA
    a. If yes → What type of job?_____

Health and Nutrition Information

25. In the past 6 months, did the caregiver suffer from any kind of illness in which she was unable to care for the child? Yes/No
    a. If yes → Who was taking care of the child? Father / Sister / Auntie / Grandmother / Other _____
    b. If yes → For how long? _____ days/months
    c. If yes → When did the sickness start? _____ days/months
26. In the past 6 months, did the caregiver/guardian suffer from any illness in which they/you were unable to work on the farm?
    a. If yes → Did this affect the child's diet? Yes/No
        i. If yes → Explain which foods were lacking to the child: Maize/Groundnuts/Pigeon Peas/Other_____ _____
27. In the past 6 months, did the father suffer from any illness in which he was unable to work on the farm? Yes/No/NA
    a. If yes → Did this lead to a decrease in the child's care? Yes/No
        i. If yes → How does this affect the child's care? For example, relative of the child is taking care of the child. Other: _____
    b. If yes → Did this make the child's food decrease? Yes/No
        i. If yes → Explain which foods were lacking to the child: Maize/Groundnuts/Pigeon Peas/Other: _____
28. In the past 6 months, was the caregiver looking after anyone else (relative/friend) such that it lead to the child's care decreasing? Yes/No
    a. If yes → how did this affect the child's care? For example, a relative was taking care of the child. _____
    b. If yes → did this affect the source of food to the child? Yes/No
        i. If Yes → Explain the foods which were lacking: Maize, Groundnut, Pigeon Pea, Other:_____
        How? Not available, child ate less, child didn't eat / or diet changed, type of food changed, food preparation and hygiene changed _____
29. In the past 6 months, did the caregiver spend much time at the farm? Yes/No
    a. If yes → how much time did she spend at the farm? _____ hours/days/weeks/months
    b. If yes → did she go with the child to the farm? Yes/No
        i. No → Who was taking care of the child? Father/Sister/Aunt/Grandmother/Other_____
30. In the past 6 months, did the caregiver go to another place for a long time for other work apart from farming? Yes/No
    a. If yes → How much time did the caregiver spend where she went? _____ hours/days/weeks/months
    b. If yes → Did she take the child? Yes/No
        i. No → Who was taking care of the child? Mother/Father/Sister/Aunt/Grandmother/Other_____
31. Did the mother go for an HIV test? Yes / No / Don't know Result:_____

a. Positive → Is she on treatment? Yes / No

32. Did the father go for an HIV test? Yes / No / Don't know Result:_____
    a. Positive → Is he on treatment? Y/N
33. Has the child gone for an HIV test? Yes / No / Don't know Result:_____
    a. Positive → Is the child on treatment? Y/N
    b. Positive → Is the child on Cotrim prophylaxis? Yes/No
34. Is anyone elder/adult in your house on TB treatment? Yes/No
35. Is the child on TB treatment? Yes/No
36. Where do you draw/fetch/get water? Borehole/River/Well
37. How long does it take you to reach where you draw/fetch water? 0-10 minutes / 10-20 minutes / 20-30 minutes / 30-60 minutes / more than
38. How many times do you fetch water per day? 0 / 1 / 2 / 3 / 4 / 5 / more than
39. Is the child breastfed? Yes/No
    a. If no → If the child is not breastfed, at what age did the child stop breastfeeding?
       _____
40. What age did the child start eating foods other than breast milk? _____
41. Does the child have a long-term disease? Yes/No
    a. If yes → What type of disease?_____

Symptoms/Illness

42. Does anybody in the household have a chronic or debilitating disease? Yes / No
    a. If yes → Who?_____
    b. If yes → What condition?_____
43. Has the child been admitted in to a health clinic/hospital in past 2 weeks? Yes/No
    a. If yes → What was the reason/illness_____
44. In the past two weeks did the child suffer from diarrhea? Yes/No
    a. If yes → If the child had diarrhea, how many days? 1 / 2 / 3 / 4 / 5 / 6 / 7 / more
    b. If yes → Was the stool mixed with blood? Yes/No
45. Does the child still have diarrhea? Yes/No
    a. If yes → If the child still had diarrhea, how many times yesterday did they have it? 1 / 2 / 3 / 4 / 5 / 6 / 7 / more.
46. Has the child suffered from skin rash in the past two weeks? Yes/No
    a. If yes → How many days did it last if the child had a rash? 1 / 2 / 3 / 4 / 5 / 6 / 7 / more.
47. Does the child have skin rash now? Yes/No
48. Has the child had a fever in the past two weeks? Yes/No
    a. If yes → If so, how many days did the fever last? ? 1 / 2 / 3 / 4 / 5 / 6 / 7 / more.
49. Does the child have fever now/still have fever? Yes/No
50. Has the child have a cough in the last two weeks? Yes/No
    a. If yes → If so, how many days did the cough last? ? 1 / 2 / 3 / 4 / 5 / 6 / 7 / more.
51. Does the child have a cough now? Yes/No
52. In the last two weeks did the child have any medicine? Yes/No
    a. If yes → What type of medicine? Describe:_____
53. Did the child eat RUTF last month? Yes/No
54. Did the child have medicine like Bactrim or penicillin in the last two weeks? Yes/No
    a. If yes → what ones? _____
55. Did the child have an allergy after taking groundnut, soya, or milk? Yes/No
56.
    a. Village: _____
    b. Directions from the study site to the caregiver's home:
       _____
       _____
       _____
       _____
57. Phone number:_____

Clinic Card

CHILD'S NAME: _____ MALE / FEMALE STUDY ID: _____

SITE: _____ TWIN: YES / NO If yes, Study ID: _____

DATE OF BIRTH: _____ (dd/mm/yy)

CAREGIVER NAME: _____ RELATIONSHIP OF CAREGIVER: _____

WEEK	DATE (dd/mm/yy)	LENGTH (cm)		WEIGHT (kg)	MUAC (cm)	EDEMA	FEVER # of days	DIARRHEA # of days	RASH # of days	Sachets of Study Food Left?	Eating Food Well?	HEALTH CENTER VISIT/MEDS	COMMENTS (about symptoms/meds/health center/compliance)	# sachets given
Start		1 2 3				Y / N +1 +2 +3					Y / N	Y / N		
2		1 2 3				Y / N +1 +2 +3					Y / N	Y / N		
4		1 2 3				Y / N +1 +2 +3					Y / N	Y / N		
6		1 2 3				Y / N +1 +2 +3					Y / N	Y / N		
8		1 2 3				Y / N +1 +2 +3					Y / N	Y / N		
10		1 2 3				Y / N +1 +2 +3					Y / N	Y / N		
12		1 2 3				Y / N +1 +2 +3					Y / N	Y / N		

OUTCOME: GRADUATE TRASFERED INPATIENT CARE DEFULT DEATH FAIL

Date graduated: _____

MISSED 1)____/_____/____ HOME VISIT:____/____/____ MISSED 2)____/_____/____ HOME VISIT:____/____/____ MISSED 3)____/_____/____ HOME VISIT:____/____/____