AN AGREEMENT TO HAVE MY CHILD PARTICIPATE IN A RESEARCH STUDY

INFORMED CONSENT FOR GROUPS 2, 3, and 4

TITLE:	A CER Study Comparing Changes in Body Composition and Parent Ratings of Quality of Life in 5-19 Year Olds as a Function of Participation in One of Four Versions of the Good NEWS 4 Kids Program (GN4K)
PROTOCOL NO:	Solutions IRB Protocol # 1304220
SPONSORS:	GoodNEWS4Kids, 2522 SE Willoughby Blvd, Stuart, FL., 34997 MannaRelief, Grand Prairie, Texas (817) 557-8700
MEDICAL MONITORS:	Harry G. Preuss, MD and Harry A. Croft, MD
INVESTIGATORS:	Gilbert R. Kaats, PhD[a], (PI); Harry G. Preuss, MD[b], Robert R. Leckie[c], MEng, LLB, Harry A. Croft, MD[d], Samuel C. Keith, BBA[a]; Patti L. Keith, BBA[a] [a] Integrative Health Technologies, Inc. San Antonio, TX 78209 [b] Professor of Medicine, Department of Physiology, Georgetown University Medical Center, Washington, DC, President American College of Nutrition [c] Business and Healthcare Consultants, San Antonio, Texas [d] Croft and Associates,
SITE(S):	Integrative Health Technologies, Inc., 5170 Broadway, Suite 5, San Antonio, TX 78209 Phone: 210.824.4200 or 210.861.2400 Fax: 210.390-6142 Email Address: grk@ihtglobal.com
STUDY-RELATED PHONE NUMBER(S):	Gilbert R. Kaats, PhD Patti Keith (Study Coordinator) 210-824-4200 210-601-8080 (24 hours)

OVERVIEW OF THE STUDY. All subjects in Groups 2, 3, and 4 in this study, will participate in the Good News 4 Kids "Standard" program (www.goodnews4kids.net) alongside one of the Good NEWS 4 Kids "Enhanced" programs. The enhanced program includes, among other components, the Kids Helping Kids (KHK) program. The KHK program matches the actual number of nutritional supplements your child consumes during the 6 month study period and provides that same amount to a disadvantaged child or orphan. All subjects participating in one of these three enhanced program groups will complete a beginning and ending body composition test, and some subjects will be consuming a calcium/vitamin D_3 supplement. The sequence of requirements for this study is as follows and each requirement is explained in further detail below:

1. review the program on the GN4K website;
2. complete the Quality of Life Study Children's Demographic Form;
3. review the Background Information;
4. complete the HIPAA Form;
5. complete the Informed Consent Form;
6. complete the Parent's Rating Form;
7. schedule and complete the Body Composition Test (DXA);
8. review Body Composition results;
9. choose which type of group in which to participate;
10. pick up product and daily tracking form and obtain measurements;
11. make daily entries of product usage one the daily tracking form;
12. take advantage of the GN4K education program;
13. complete monthly ratings, product usage and measurements;
14. complete ending body composition, hip and waist measurements, and turn in the final daily tracking form;
15. review test results and complete an End of Study Critique; and
16. select child/orphan to whom you want the supplements to be provided.

1. Review the program on the GN4K website (www.goodnews4kids.net) and

2. Complete the Quality of Life Children's Demographic Form.

3. Background Information. For decades America's approach to improving the health of our children has been to encourage consumption of more fruits and vegetables, reduce the number of calories they eat, and increase their exercise. However, an increasing number of studies are suggesting that this approach, while helpful, has fallen far short of achieving national goals. Studies have been reporting "malnourishment" in children who are actually overfed. Even obese children have been found to be micronutrient-deficient in spite of their overconsumption of foods. While there are complex explanations the poor health of our youth, four habits that stand out are (1) poor nutrition, (2) low levels of physical activity, (3) poor sleep habits, and (4) inadequate consumption of drinking water. Good NEWS 4 Kids (GN4K) has developed a program to augment and supplement current efforts to curtail this trend.

Concerning the consumption of fruits and vegetables, studies suggest that a growing problem is the fact that our fruits and vegetables are increasingly lacking in micronutrients due to some of our modern farming practices. The GN4K program addresses this problem by supplementing children's diets with "MannaBears™"--a food-sourced micronutrient supplement in a highly palatable "gummy bear" that previous studies have found children are more likely to consistently eat.

Another key component of the GN4K program is to increase the participating parents' health awareness, or "health literacy." With regard to health awareness, a recent study by the Harvard School of Public Health and the Robert Wood Johnson Foundation found that only 15% of parents said their children are a little to very overweight, while in actuality, 32% of children are overweight or obese. In addition, only 20% of parents expressed concern that their child's weight would result in the overweight child becoming an overweight adult—a figure less than one-third of the 70% of American adults who are overweight or obese. The researchers suggest that this lack of awareness is a "national emergency" and that

"Better nutrition and more physical activity can help turn this epidemic around, and parents have a unique role to play. Knowing the risks of obesity and dealing with the issue proactively can improve kids' health now and prevent serious problems down the road."

With regard to health literacy, the U.S. Surgeon General has recently stated that "…increasing health literacy if the most important thing a healthcare provider can do." Therefore, throughout the program, GN4K provides parents with summaries of the latest research on nutrition, exercise, sleep, and water consumption, as well as on-going updates of research in these program components as they become available. GN4K also goes a step further by personalizing this information to you and your child in order to take advantage of the benefits of "self-monitoring." Self-monitoring has been found to have a profound effect on changing behavior as it has become increasingly clear that:

1) what gets measured, gets managed,

2) what gets measured and tracked, gets managed even better; and

3) what gets measured, tracked and compared to existing standards gets managed best of all.

Parents will also be asked to rate their child's habits and behavior, and obtain measurements of height, weight, hip and waist at the beginning, at the end of each month, and at the conclusion of the study. To meet these health awareness and literacy goals, we will provide you with the latest standards or norms from the U.S. Centers for Disease Control and other studies to enable you to compare your child's measurements at the start and monthly throughout the study.

In a small pilot study of a preliminary version of the GN4K program, an independent research team (www.ihtglobal.com) found that among children aged 6-18 who followed the program for two-months, 77% lost excess body fat, 85% increased metabolically active lean mass, and 92% improved their bone density or bone health. Additionally, parents who rated their child's behavior at the beginning and end of the two-month study reported noticeable improvements in a wide number of health-related behaviors.

4. **Complete the HIPPA Form.** Complete the Health Insurance Portability and Accountability Act (HIPAA) form (which can be found at the end of this document) before providing us with any personal information regarding your child or giving your consent. This is our assurance that all of the data we collect will be treated as confidential research information. Instead of using your child's name, we will assign a study subject number to your child or children that will be used throughout the study. Other than you, the senior investigator is the only one who will be able to link your child's study number to his/her name.

HIPAA FORM

Health Insurance Portability and Accountability Act

Authorization (Permission) to Use or Disclose (Release)
Protected Health Information (PHI) for Research

TITLE: A CER Study Comparing Changes in Body Composition and Parent Ratings of Quality of Life in 5-19 Year Olds as a Function of Participation in One of Four Versions of the Good NEWS 4 Kids Program (GN4K)

PRINCIPLE INVESTIGATOR: Gilbert R. Kaats, PhD, 5170 Broadway, Suite 5, San Antonio, Texas, 78209

1. What is the purpose of this form?
This form is required by the Health Insurance Portability and Accountability Act of 1996. Specifically the privacy regulation (HIPAA) permits the research investigators listed above to use and disclose health information about you for the research study identified above which has been approved by the Solutions Institutional Review Board. Integrative Health Technologies would like to use your protected health information for research. The elements of protected health information that are related to this study as defined by HIPAA are listed below.

Data Elements for Protected Health Information (PHI)

- Names
- All geographic subdivisions smaller than a state (except for the first 3 digits of the zip code in some cases)
- All elements of dates (except year) for dates directly related to an individual (e.g., birth date, admission date, discharge date, date of death) and all ages over age 89 and dates indicative of that age
- Telephone numbers
- Fax numbers
- E-mail addresses

2. What protected health information do the researchers want to use?
Integrative Health Technologies will acquire measurements of your body composition (lean, fat and bone mass) blood chemistries and self-reported information derived completion of a Quality of Life Questionnaire and weekly tracking forms as shown in the Informed Consent. The researchers will replace your name and any other personal identifier on these forms with a randomly-selected study subject number. A list of what subject received what study number will be retained by the Principal Investigator and NOT released or shared with the study Sponsor or anyone else without your written permission.

3. Why do the researchers want my protected health information?
Integrative Health Technologies will need the above health information in order evaluate the effects of the two weight loss supplements we are studying.

4. Who will be able to use my protected health information?
Integrative Health Technologies will use your health information solely for this research study. As part of this research, they may give your anonymous study data to the sponsor, U.S. regulatory agencies and publish the findings in a peer-reviewed medical journal. However, at no time will your name be identified with your subject number.

5. How will information about me be kept private?
(See number 2 above)

6. What happens if I do not sign this permission form?

If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. If I sign this form, will I automatically be entered into the research study?
No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form. Treatment by your physician will not be affected by whether you provide authorization for the requested use or disclosure except if your treatment is related to research.

8. What happens if I want to withdraw my permission?
You can change your mind at any time and withdraw your permission to allow your protected health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new protected health information will be used for research. However, researchers may continue to use the protected health information that was provided before you withdrew your permission. If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.
To withdraw your permission, please contact the person below. He/she will make sure your written request to withdraw your permission is processed correctly.

9. How long will this permission last?
If you agree by signing this form that researchers can use your protected health information, this permission has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding access to my personal health information?
You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your protected health information kept by Integrative Health Technologies. You do not have the right to review and/or copy records kept by the researchers associated with the research study.

Contact Name:	Gilbert R. Kaats, Phd
Contact Address:	5170 Broadway, Suite 5, San Antonio, Texas 78209
Contact Phone, FAX:	210-824-4200 210-390-6142

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Signatures
I agree that my protected health information may be used for the research purposes described in this form.

Patient Signature:_____ Date: _____

or Legal Representative: _____ Date: _____

Printed Name of Legal Representative (if any): _____

5. Complete the Parent's Baseline Rating Form. You will be asked to complete the Parents' Baseline Rating Form once you have signed the HIPAA form. This will give us an idea of the areas in which you think your child needs improvement.

6. Electronically sign this Informed Consent Form at which point you have a full and complete understanding of its contents.

7. Complete the Body Composition Test. This FDA-approved test is considered to be the gold standard for measuring bone strength, lean mass and body fat—a test that typically cost of over $200. The DXA test is described at Attachment 6. Parents are also encouraged, but not required, to take a complementary DXA test at the beginning of the study to better understand what is being measured in their child.

8. Review Body Composition Results. Upon completion of the test, parents will be provided their child's test results (and, if applicable, their own results) with comparisons to norms for age and gender.

9. Choose the type of group in which you would like your child to participate. After reviewing test results, parents will have the option of enrolling their child in one of two study groups—one group provides a calcium/vitamin D_3 supplement, the other group does not provide or require the child to take this supplement.

10. Pick up product and daily tracking form, and obtain a scale weight. You will need to return to the research center in order to receive your first month's supply of MannaBears™ and tracking form. A state of the art scale will be provided for your child in order to obtain a scale weight. A research technician will also obtain a hip and waist measurement on your child on this first visit. See item number 13 for instructions on obtaining subsequent measurements.

11. Make daily entries of product usage on the daily tracking form. Your child will be asked to take four (4) MannaBears™ each day, and will be required enter the number of he/she actually took each day. Even if he/she does not consume any MannaBears™ on a particular day, it must still be entered as a zero on that day. This action will ensure that an underprivileged child or orphan will still receive the full bottle of MannaBears™ for that month. The only situation whereby the underprivileged child will not receive the MannaBears™ is in the case of your child failing to record anything on the daily form and leaving the space blank.

12. Follow the Good News 4 Kids program. This program is designed to provide you with an on-going stream of information related to the four behaviors the program is designed to improve: nutrition, physical activity levels, quality sleep and drinking more water. As you move through this 3-month highly informative program, you will be able to access articles, videos and research studies related to these four program outcomes. The GN4K staff will also be available to answer questions or resolve any difficulties you are having with the educational and motivational material they will be providing you.

13. Complete monthly ratings, product usage, and measurements. Each month, you must obtain a scale weight and take measurements of your child's hip and waist. The scale weight can be obtained at the research center on the same scale you used when you picked up your initial supply of product. This will be done when you come in to the center for your monthly supply. However, you will responsible for taking and recording your child's hip and waist measurements at your convenience. You will be provided with a retractable tape measure in order to do so. You will also be required to fill out the Parent's Monthly Rating Form at the end of each month of the study. An email will be sent to you with a link that will direct you to the form.

14. Schedule and complete your child's ending body composition test and hip and waist measurements, and turn in the final daily tracking form.

15. Return to the research center to review test results and complete an End of Study Critique.

16. Select child/orphan to whom you want the supplements to be provided. At the conclusion of the study, we will summarize the number of nutritional supplements the participant reported during the study and provide you with a list of organizations and people supporting disadvantaged or orphaned children. You may pick the organization to whom you want your contribution to be made. In most cases, this organization will be in your home town. You may also write a brief note from you personally encouraging the recipient to take the supplements to improve their health or simply have them sent anonymously.

We will notify GN4K that you have completed all the necessary forms to begin the study. GN4K will continue to contact with you throughout the 3-month program providing you and your child with relevant information and encouragement.

Benefits:

- Based on the pilot study of this program and related research, there is compelling evidence to suggest that increasing micronutrient intakes, physical activity, sleep, and consumption of drinking water will improve body composition and quality of life, and will lead to other health benefits, all with no evidence of adverse effects;
- A six month's supply of MannaBears™ (a total value of ~$180);
- An opportunity to examine the effects of the MannaBears™ supplement before purchasing it on the open market. Please contact GN4K at www.goodnews4kids.net for more information on how you can purchase MannaBears™.
- At the end of the 3-month study period, participants may apply to GN4K to continue the program for an additional three months.

Potential Risks to Participants: Some potential risks related to your child's involvement in this study include allergic or other symptomatic reaction to the MannaBears™. If you experience any allergic reactions or other adverse effects at any time during this study, you should immediately discontinue product use, notify the researchers, and contact your medical care provider. However, GN4K, the Sponsor, nor the research company will provide medical services or financial assistance for injuries or other medical conditions that might occur.

Subject Eligibility: In order to participate, you must:

- be between the ages of 5-19

- agree to follow the requirements of the study as set forth in this Informed Consent;
- complete all required forms as described on GN4K and the researchers' websites;
- meet the selection criteria for enrollment in the study.

In order to participate, all children must obtain permission from his/her parent or guardian and both the child and the parent or guardian must complete the Informed Consent Form.

New Findings: During the study, you may be provided with any important new findings about the study supplements. You may use this information in your decision to have the child continue in the study.

Alternatives to Participation: This study is being done for research purposes only and the child's participation is voluntary.

In Case of Research Related Injury: Neither Integrative Health Technologies, Inc., Good News 4 Kids, MannaRelief, nor the sponsoring organization will provide medical services or financial assistance for injuries or other medical conditions that might occur because your child is taking part in this research.

Legal Rights: You do not waive any of your legal rights by signing this document.

Confidentiality: All data acquired in this study will be accorded the confidentiality as set forth in the Health Insurance Portability and Accountability Act of 1996 for Research Form, "*Authorization (Permission) to Use or Disclose (Release) Protected Health Information*, that you are required to sign in conjunction with this study.

Whom to Contact: Contact the research center at 210-824-4200 or GN4K@ihtglobal.com or 210-601-8080 (24 hours emergency number) for any of the following reasons:

- if you have any questions about the child's participation in this study,
- if at any time you feel the child has had a research-related injury or a reaction to the study supplement, or
- if you have questions, concerns or complaints about the research

If you have questions about the child's rights as a research subject or if you have questions, concerns or complaints about the research, you may contact Solutions IRB

Solutions IRB is an OHRP approved board of medical and lay people who will conduct an independent review of this research to ensure the risks to which you will be exposed and the benefits you receive are explicitly stated and are not excessive. They will not be able to answer some study-specific questions, such as questions about appointment times. However, you may reach them at review@solutionsirb.com or call 1-855-226-4472 if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Voluntary Participation: The child's participation in this study is voluntary. You may decide not to participate and or he/she may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. If you have any questions about the research study, tests, supplements, your rights as a participant, or if you wish to withdraw from the study, contact Dr. Kaats or the Research Coordinator at (210) 824-4200.

Your participation in this study may be stopped at any time by the investigator without your consent for any of the following reasons:

- if the investigator has documented evidence that participation is not in the child's best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect the child.

You will be given a copy of this dated and signed consent form.

Consent: I have read the information in this consent form and freely consent to participate in the study. If I had any questions about the study, I contacted the research group and those questions about the study and my participation in it have been answered.

CONSENT DISCUSSION. I CONFIRM THAT THE RESEARCH STUDY WAS THOROUGHLY EXPLAINED TO THE SUBJECT. I REVIEWED THE CONSENT FORM WITH THE SUBJECT AND ANSWERED THE SUBJECT'S QUESTIONS. THE SUBJECT APPEARED TO HAVE UNDERSTOOD THE INFORMATION AND WAS ABLE TO ANSWER THE FOLLOWING QUESTIONS CORRECTLY:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Are you going to receive any monetary payment for your participation?
8. Do you have to be in this study?
9. If you decide to be in the study, can you leave the study when you want to?
10. What options do you have if you decide not to continue in the study?
11. Will you receive the remainder of the supplement at which time you decide not to continue?

_____ _____

PRINTED NAME OF PERSON CONDUCTING THE INFORMED CONSENT (IC) DISCUSSION | POSITION

_____ _____

SIGNATURE OF PERSON CONDUCTING THE IC DISCUSSION | DATE

_____ _____

Printed Name of participating child (First, Middle Initial, Last) | Date of Birth

_____

Mailing Address

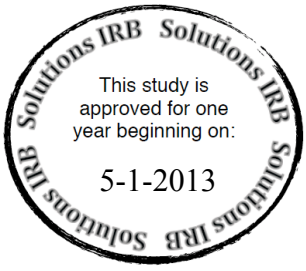
_____ _____

Primary E-Mail | Secondary E-Mail (if applicable)

---------- _____ _____

Cell Phone | Home Phone | Work Phone

Note: Your cell phone will be called initially. Please indicate if you prefer not to be contacted at this number



_____ _____ _____

Signature of the participating child | Date | Witness

_____

Printed Name of Parent

_____ _____

Signature of Parent | Date | Witness