

# AN AGREEMENT TO HAVE MY CHILD PARTICIPATE IN A RESEARCH STUDY

## INFORMED CONSENT FOR GROUP 1

**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<sup>a</sup>, (PI); Harry G. Preuss, MD<sup>b</sup>, Robert R. Leckie<sup>c</sup>, MEng, LLB, Harry A. Croft, MD<sup>d</sup>, Samuel C. Keith, BBA<sup>a</sup>; Patti L. Keith, BBA<sup>a</sup>

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**STUDY-RELATED  
PHONE NUMBER(S):**

Gilbert R. Kaats, PhD  
Patti Keith (Study Coordinator)  
210-824-4200  
210-601-8080 (24 hours)

**Background.** We have received the information from the Children's QOL Study Demographic Form for your child's participation in our study, and confirmation that you have reviewed the study requirements which are outlined in the FAQs tab on the Home Page of the GN4K website [www.goodnews4kids.net](http://www.goodnews4kids.net). Before providing you with the forms you will be required to complete, it's important to understand the previous research that led to this study.

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 is 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.*

GN4K is asking parents to record their child’s habits and behavior, and obtain measurements of height, weight, hip and waist at the beginning of the program, at the end of each month, and at the conclusion of the program. To meet these health awareness and literacy goals, GN4K 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](http://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.

**Study Requirements:**

1. Complete the Health Insurance Portability and Accountability Act (HIPAA) form below before providing us with any personal information regarding your child. 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): \_\_\_\_\_

2. Once you complete the HIPAA form, and this Informed Consent, you will be asked to complete the Parents' Baseline Rating Form below. This will give us an idea of the areas in which you think your child needs improvement. You may continue to read and review the Study Requirements and come back and complete this Rating Form before you give consent at the end of this Informed Consent Form document.

**BEGINNING QUESTIONNAIRE.** Your answers are confidential research information and will not be released to anyone without your written permission. Please indicate the extent to which your child needs improvement in each of the 25 behaviors listed below using the following 5-point rating scale:

**1=NO IMPROVEMENT NEEDED**

**2=SLIGHT IMPROVEMENT NEEDED**

**3= SOME IMPROVEMENT NEEDED**

**4=CONSIDERABLE IMPROVEMENT NEEDED**

**5= A GREAT DEAL OF IMPROVEMENT NEEDED**

1. Exercising enough	1... 2... 3... 4... 5
2. Enough physical activity other than exercise	1... 2... 3... 4... 5
3. Sleeping habits	1... 2... 3... 4... 5
4. Drinking enough water	1... 2... 3... 4... 5
5. Healthy eating habits	1... 2... 3... 4... 5
6. Eating enough fruits	1... 2... 3... 4... 5
7. Eating enough vegetables	1... 2... 3... 4... 5
8. Watching too much television	1... 2... 3... 4... 5
9. Spending too much time on the computer	1... 2... 3... 4... 5
10. Not enough restful sleep	1... 2... 3... 4... 5
11. Difficulty in getting up in the morning	1... 2... 3... 4... 5
12. Napping or falling asleep during the day	1... 2... 3... 4... 5
13. Willingness to do his/her homework	1... 2... 3... 4... 5
14. Playing too many video games	1... 2... 3... 4... 5
15. Too much texting friends	1... 2... 3... 4... 5
16. Staying home from school because of illness	1... 2... 3... 4... 5
17. School grades	1... 2... 3... 4... 5
18. Willingness to go to school	1... 2... 3... 4... 5
19. Overall happiness	1... 2... 3... 4... 5
20. Paying attention in school	1... 2... 3... 4... 5
21. Getting along with other members of the family	1... 2... 3... 4... 5
22. Eating too many fast foods	1... 2... 3... 4... 5
23. School grades	1... 2... 3... 4... 5
24. Napping or falling asleep during the day	1... 2... 3... 4... 5
25. Overall health	1... 2... 3... 4... 5

**Please provide or obtain the following measurements:**

26. Date this form was completed	
27. Gender	
28. Birth date	
29. Ethnic background	
30. Scale weight measurement	
31. Height measurement	
32. Hip measurement (instructions on reverse side)	
33. Waist measurement (instructions on reverse side)	

3. Throughout the study your child will be asked to consume four MannaBears™ a day and to record the actual number of MannaBears™ taken each day on a written form. You will receive this written form at the same time you pick up your initial and monthly supply of product. All your child has to enter on this form is the actual number of MannaBears™ he/she took each day of the study and enter “0” on any day that none

were consumed. At the end of each month of the study, you will also be required to fill out the Monthly Parent Rating Form indicating how much or how little progress your child has made in each of the areas. You will also enter the total number of MannaBears™ your child consumed that month. You will be reminded each month by email to fill out these forms which can be accessed on the research groups' website.

4. We will notify GN4K that you have completed all the necessary forms to begin the study. GN4K will then provide you with information on where you can pick up the first month's supply of the MannaBears™ and the Daily Tracking form. GN4K will continue to contact with you throughout the 6-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](http://www.goodnews4kids.net) for more information on how you can purchase MannaBears™.

**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](mailto: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](mailto: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.

\_\_\_\_\_  
Printed Name of participating child (First, Middle Initial, Last)

\_\_\_\_\_  
Date of Birth

\_\_\_\_\_  
Mailing Address

\_\_\_\_\_  
Primary E-Mail

\_\_\_\_\_  
Secondary E-Mail (if applicable)

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Cell Phone

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

\_\_\_\_\_  
Home Phone

\_\_\_\_\_  
Work Phone

\_\_\_\_\_  
Signature of the participating child

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Printed Name of Parent

\_\_\_\_\_  
Signature of Parent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

