

## SUBJECTS' INFORMED CONSENT

*A Research Study Evaluating the Safety and Efficacy of a Plant-sourced Pollen Extract Supplement Designed to Reduce Nocturia, Improve Sleep, Improve Body Composition and Quality of Life*

**SPONSOR:** Gramenix, Inc., 300 County Road C, Dashler, OH, 43516

**INVESTIGATORS:** Gilbert R. Kaats, PhD<sup>a</sup>; Harry G. Preuss, MD<sup>b</sup>; Larry K. Parker, Sr, MD<sup>c</sup>

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**SITE(S):** Integrative Health Technologies, Inc., 5170 Broadway, Suites 1, 2 & 5, San Antonio, Texas 78209

**STUDY-RELATED PHONE NUMBER(S):** Gilbert R. Kaats, Ph.D., 210-824-4200, Mike Gale, (Study Supervisor): 210-824-4200, 210-275-9173 (24 hours)

**Purpose:** As the average age of women in our society steadily increases, so too has the number of women suffering from poorly controlled bladder functioning that can have troubling effects on sleep quality and general quality of life. Previous studies with males have shown improvements in lower urinary tract symptoms when taking *Cernitin*<sup>®</sup>, a flower pollen extract. Anecdotal reports from the men's spouses suggested improvements in their urinary control when taking Cernitin. Although we could find no supporting studies of its effects on women, there are a number of studies supporting positive effects on urinary control in women who consumed Pumpkin seed extract. The purpose of this study is to examine which of three different combinations of *Cernitin* and Pumpkin seed extract are most effective in improving daytime and nighttime urinary control in women. Data derived from pilot studies have also suggested that consumption of this product has been associated with self-reported improvements in quality of life and measures of blood pressure and improved body composition by depleting fat without significant adverse effects on bone or muscle mass. However, with the exception of urinary control, these latter changes were derived from small, short-term pilot studies and should be viewed only as preliminary findings to be further evaluated.

**Requirements:** Since the primary goal of this study is to assess the extent to which the product has an effect on urinary control, to participate, you must indicate that this is a problem, no matter how minor, so you can rate any changes when taking the product. You will be asked to make a rating as to the severity of your problem before actually enrolling. If you think you can detect a change, you will also be asked to complete the following baseline, mid-study and ending tests:

- 45-item Blood Chemistry Panel (Atch 1);
- Self-reported Quality of Life Inventory (QOL) (Atch 2);
- Questionnaire for Female Urinary Incontinence Diagnosis (QUID) (Atch 3);
- Weekly reports of possible side effects and discomfort from product (Atch4); and
- Sample DEXA scan report of bone density, lean & fat mass Baseline & ending only (Atch 5).

**Potential Risks:** Allergic or other symptomatic reactions to the product: Although the ingredients used in this product are considered "generally regarded as safe" (GRAS) by the U.S. Food and Drug Administration, there is always a chance of allergic reactions. Therefore, you should consult with your medical care provider prior to your involvement in the study. If you experience any allergic reactions or other adverse effects at any time during this study, you should discontinue product use, notify the researchers, and contact your medical care provider. Clearance from your medical care provider will be required before you will be permitted to continue in the study.

**Benefits:**

- Three-fourths of the subjects will receive a 120-day supply of a variation of the Graminex supplement;
- If you receive an inactive placebo product, you will be provided with a 4-month supply of the product that was found to be most effective;
- You will receive three comprehensive blood chemistry tests—a total value of ~\$1,300, two DEXA Total Body Scans—a total value of ~\$450;
- You can receive up to \$265 for your participation and the timely recording of your actual daily product usage NO MATTER HOW MUCH OR HOW LITTLE PRODUCT YOU TOOK. Although we want you to take the product as prescribed, these fees are being paid not as an incentive to take the product, but rather for honestly reporting how much of the product you actually took.
- You may be entitled to participate in future studies, including a possible extension of this study;
- Your participation will provide important scientific information that may be beneficial to others (See Atch 6 on the benefits of participating in a clinical trial.)

**In order to participate, you must complete the initial question on difficulty with urinary control and**

- be an English-speaking female at least 18 years of age;
- agree to follow the requirements of the study as set forth in this Informed Consent;
- agree to withdraw from the study if you become pregnant during the study

**You cannot participate if you:**

- Do not speak English
- Are under 18 years of age
- Are pregnant or nursing
- Are diabetic
- Have uncontrolled hypertension
- Had major surgery two weeks prior to enrolling
- Are undergoing infertility treatment
- Known cardiovascular disease
- Had a bypass or now have a stent
- Your physician recommends against participation.

**Study Procedures: A Checklist for Participation.** If you meet the eligibility requirements for inclusion in the study and wish to be a participant, PLEASE INITIAL each of the steps listed below to ensure you understand the requirements for the study.

1. \_\_\_\_\_ I meet the inclusion/exclusion criteria set forth above
2. \_\_\_\_\_ I have read this Informed Consent, the additional information on the website and have met with the research coordinator to ensure I understand what will be expected of me. ([www.ihtresearch.com](http://www.ihtresearch.com))
3. \_\_\_\_\_ I acknowledge that I have had the opportunity to review this Informed Consent with my physician or healthcare provider to ensure that I have no medical conditions that would prevent my participation.
4. \_\_\_\_\_ I am willing to participate in this study and acknowledge that upon signing this informed consent, I will be enrolled as a participant.
5. \_\_\_\_\_ The study materials and supplement will be provided at no cost to me.

6. \_\_\_\_\_ I agree to complete all required tests shown below.
7. \_\_\_\_\_ No later than 3 days after the end of each study day, I will record how much product I took each day and any adverse effects I think are attributable to the product at [study.ihresearch.com](http://study.ihresearch.com)
8. \_\_\_\_\_ I will visit the Research Center at the end of 60 days to complete mid-study tests.
9. \_\_\_\_\_ I agree to **fast for at least 10 hours** prior to having my blood drawn at the Quest drawing station of my choosing within 5 DAYS OF THE BASELINE, MID-POINT AND END OF THE STUDY.

**Payments for Testing:** If you complete all study requirements, you can receive a \$25 registration fee and a “tracking fee” for each day that you have recorded your product usage within 3 days after each study day. Assuming you complete all study requirements, you will receive these fees as follows:

- \$25 immediately upon completion of all baseline requirements;
- up to \$120 immediately after completing the mid-study tests providing you completed your tracking information as set forth above;
- up to \$120 immediately upon completion of the end-of-study tests.

**Participant Time Involved:** The total time required for the study is approximately 10 hours over the 90-day study period. This time includes completion of the Informed Consent Form, meeting with the research coordinator, completion of the required tests and questionnaires, on-line reporting, study critique, and travel and wait times.

**Unknown effects:** Although there are no known adverse effects from the supplement, you are asked to review your participation with your personal physician to insure you have no medical conditions that would prevent your participation.

**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 continue in the study.

**Alternatives to Participation:** This study is for research purposes only and your participation is voluntary.

**In Case of Research Related Injury:** Neither Integrative Health Technologies, Inc. nor the study sponsor will provide medical services or financial assistance for injuries or other medical conditions that might occur because you are taking part in this research. However, if you have any injuries that you think are attributable to the study, call Mike Gale (210-824-4200 or 210-275-9173) or Dr. Kaats (210-241-4900).

**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 (HIPPA) Form, “*Authorization (Permission) to Use or Disclose (Release) Protected Health Information*”, that you are required to sign.

**Whom to Contact:** Contact Mike Gale at 210-824-4200 or 210-275-9173 (24 hours) if:

- you have any questions about your participation in this study,
- at any time you feel you have had an adverse reaction to the study supplement,
- you have questions, concerns or complaints about the research

If you have questions about your 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. You may reach them at [reviews@solutionsirb.com](mailto:reviews@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:** Your participation in this study is voluntary. You may decide to 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 the Study Supervisor (Mike Gale) or Dr. Kaats at the numbers provided above.

Your participation in this study may be stopped at any time by your physician or healthcare provider without supporting information. Participation may also be stopped by the study's principal investigator upon receipt of information that either the product has unexpected adverse effects or that changes in the study protocol are inconsistent with information provided to you in this Informed Consent. Notwithstanding these conditions, this Consent Form is the sponsor's agreement to provide all services listed in this form including conducting all tests, providing test reports, and payment of the tracking fees at the end of the study for subjects who have completed all testing.

**Consent:** I have read the information in this consent form. All my questions about the study and my participation in it have been answered. I freely consent to be in this research study. None of my medical records are being requested for this study.

**Please select a user name and a password for on-line access for reporting our data.**

Your name \_\_\_\_\_

User Name \_\_\_\_\_ Password: \_\_\_\_\_

Address: \_\_\_\_\_ Zip Code: \_\_\_\_\_

E-mail Address: \_\_\_\_\_

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Telephone Contact

**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 answered the following questions:

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. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?
9. What do you need to do in order to be paid the tracking/reporting fees?
10. What options do you have if you decide not to continue in the study? Will you still be paid?

\_\_\_\_\_  
Signature of Person & Date

\_\_\_\_\_  
Research Coordinator

**Atch 1. 45-measure fasting blood chemistry measurements**

<b>The 45-Measurement Blood Test</b>			
1	CHOLESTEROL, TO TAL	16 ALKALINE PHOSPHATASE	31 LYMPHO CYTES
2	HDL CHOLESTEROL	17 ALT	32 MCH
3	NON-HDL CHOLESTEROL	18 AST	33 MCHC
4	CHOL/HDL RATIO	19 BASOPHILS	34 MCV
5	LDL CHOLESTEROL	20 BILIRUBIN, TO TAL	35 MONOCYTES
6	TRIGLYCERIDES	21 BUN/CREATININE RATIO	36 NEUTROPHILS
7	CARDIO CRP	22 CALCIUM	37 PLATELET COUNT
8	GLUCOSE	23 CARBO DIOXIDE	38 POTASSIUM
9	ABSOLUTE BASOPHILS	24 CHLORIDE	39 PROTEIN, TO TAL
10	ABSOLUTE EOSINOPHILS	25 CREATININE	40 RDW
11	ABSOLUTE LYMPHO CYTES	26 EOSINOPHILS	41 RED BLOOD CELL COUNT
12	ABSOLUTE MONOCYTES	27 GLOBULIN	42 SODIUM
13	ABSOLUTE NEUTROPHILS	28 GSR	43 TSH W/REFLEX TO FT4
14	ALBUMIN	29 HEMATO CRIT	44 UREA NITROGEN (BUN)
15	ALBUMIN/GLOBULIN RATIO	30 HEMOGLOBIN	45 WHITE BLOOD CELL COUNT

## Atch 2. Self-reported Quality of Life Inventory

Quality of Life Difficulties (QOL)														
For each of the following conditions, select the item that best describes your condition within the last thirty (30) days. 0=No Problem 1=Minor 2=Major 3=Severe														
	0	1	2	3		0	1	2	3		0	1	2	3
1. Headaches	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	30. Feeling Weak	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	59. Sleepy Throughout the Day	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Irritable Bowel Syndrome	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	31. Eating Too Rapidly	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	60. Difficulty in Making Decisions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Arthritis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	32. Eating After Being Full	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	61. Feeling Restless	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Premenstrual Syndrome	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	33. Embarrassed About Overeating	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	62. Getting More Tired Than Usual	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Recurring Sinus Infections	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	34. Depressed Over Eating Habits	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	63. Blaming Myself Too Often	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Tension Fatigue Syndrome	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	35. Depressed About My Weight	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	64. Causing Problems for Others	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Recurrent Anxiety	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	36. Difficult to Stop Eating	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	65. Worrying About My Faults	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Recurrent Depression	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	37. Worrying About the Future	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	66. Wondering If Life is Worth Living	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Insomnia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	38. Unable to Concentrate	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	67. Suicidal Thoughts and Worries	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Low Self Esteem	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	39. Forgetfulness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	68. Decreasing Interest in People	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Binge Eating	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	40. Bad Temper or Quick to Anger	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	69. Decreasing Interest in Activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Chronic Tension	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	41. Indigestion	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	70. Difficulty in Sitting or Standing Still	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Lack of Energy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	42. Diabetes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	71. Often Fidgety	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Food Allergies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	43. Vomiting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	72. More Tired Than Usual	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. Feeling Under Stress	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	44. Heartburn	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	73. Generalized Depression	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. Cancer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	45. Esophageal Reflux	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	74. Difficulty in Finishing Activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. Prostate Problems	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	46. Control Over My Appetite	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	75. Feeling Sad Too Much of the Time	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. Overeating	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	47. Ability to Relax	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	76. Dieting Too Often	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. Stomach Pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	48. Heart Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	77. Difficulty in Staying With a Diet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. Back Pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	49. Fibromyalgia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	78. Difficulty in Getting Up in the Morning	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. Pain in Arms, Legs or Joints	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	50. Difficulty in Falling Asleep	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	79. Eating Too Much Between Meals	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22. Menstrual Pain or Problems	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	51. Awakening During the Night	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	80. Eating Too Much During Meals	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. Chest Pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	52. Feeling Sad	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	81. Getting Tired Too Often	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24. Dizziness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	53. Waking Up Too Early	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	82. Preoccupied with Gloomy Thoughts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
25. Diarrhea	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	54. Sleeping Too Much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	83. Thinking Too Much About Death	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
26. Irregular Heartbeat	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	55. Unintentional Weight Gain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	84. Slowing Down of My Thinking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
27. Shortness of Breath	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	56. Unintentional Weight Loss	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	85. Unhappy Too Much of the Time	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
28. Constipation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	57. Inability to Concentrate	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	86. Difficult to Stop Eating Once I Start	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
29. Stomach Gas or Indigestion	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	58. Satisfied With My Life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<i>Continued on reverse...</i>				

## Atch 3. Urinary Control Scale

Quality of Life Difficulties (QOL)				
For each of the following conditions, select the item that best describes your condition within the last thirty (30) days. 0=No Problem 1=Minor 2=Major 3=Severe				
	0	1	2	3
87. Poor daytime urinary control	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
88. Poor nighttime urinary control	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
89. Getting up to urinate too many times at night	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	0	1	2	3	4 or more
90. How often do you do Kegel's exercise each day?	<input type="radio"/>				

	0	1	2	3	4	5
	it is not a problem	1-5 yrs	6-10 yrs	11-15 yrs	16-20 yrs	more than 20 yrs
91. With regard to urinary control, how long has it been a problem?	<input type="radio"/>					

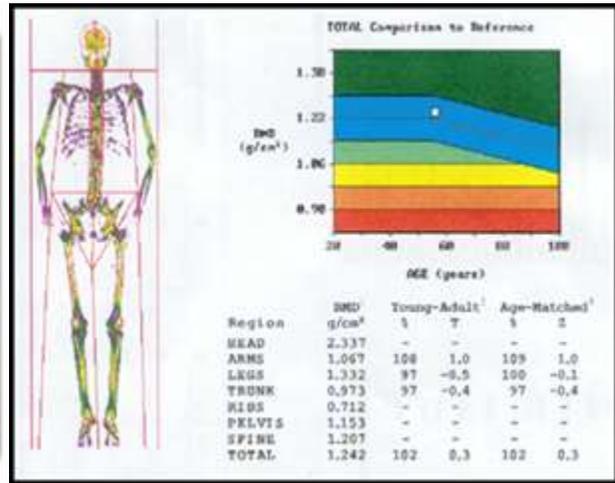
	0	1	2	3	4	5
	none of the time	rarely	once in a while	often	most of the time	all the time
Do you leak urine (even small drops), wet yourself, or wet your pads or undergarments...						
92. when you cough or sneeze?	<input type="radio"/>					
93. when you bend down or lift something up?	<input type="radio"/>					
94. when you walk quickly, jog, or exercise?	<input type="radio"/>					
95. while you are undressing in order to use the toilet?	<input type="radio"/>					
96. Do you get such a strong and uncomfortable need to urinate that you leak urine (even small drops) or wet yourself before reaching the toilet?	<input type="radio"/>					
97. Do you have to rush to the bathroom because you get a sudden, strong need to urinate?	<input type="radio"/>					

**Atch 4. Weekly tracking report**  
**(Login at: [study.ihtresearch.com](http://study.ihtresearch.com))**

**Take 1 in the AM and 1 in the PM. Store in a cool, dry place.**

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
AM	<input type="checkbox"/>																			
PM	<input type="checkbox"/>																			
Day	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
AM	<input type="checkbox"/>																			
PM	<input type="checkbox"/>																			
Day	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60
AM	<input type="checkbox"/>																			
PM	<input type="checkbox"/>																			

**Atch 5. Why Take a DEXA Total Body Scan?**



Historically, the DEXA tests has been used only to measure bone mineral density (BMD) for assessing the risk of bone of fractures and to diagnose osteoporosis by measuring bone mineral density (BMD) in the hip and spine. However, recent advances in the software have enabled us to expand the measurements to all bones in your body as well as in different regions of the body (arms, legs, trunk, ribs, pelvis, and in the total spinal column). The sample report form above is what you will receive for each DEXA test you take in the study. The report provides a picture of your skeleton along with the areas that were measured (arms, legs, trunk, etc. A brief summary of the advantage of knowing your bone density is provided in the article below followed by information about the safety of the test since it is a very low level x-ray. In reality, you won't receive as much radiation as you would get from a cross-country flight—about 1/200<sup>th</sup> of what you receive from a day in our current environment.

**A Word About Minimizing Radiation Exposure.** Special care is taken during x-ray examinations to use the lowest radiation dose possible while producing the best images for evaluation. National and international radiology protection councils continually review and update the technique standards used by radiology professionals. State-of-the-art x-ray systems have tightly controlled x-ray beams with significant filtration and dose control methods to minimize stray or scatter radiation. This ensures that those parts of a patient's body not being imaged receive minimal radiation exposure.

# Sample Report from the DEXA Total Body Scan

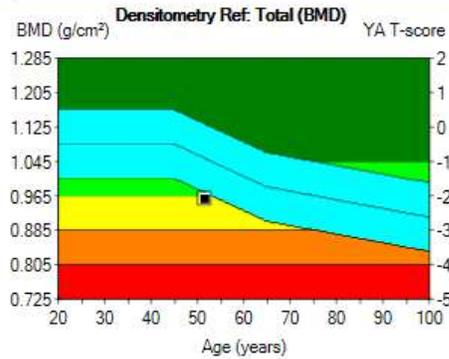
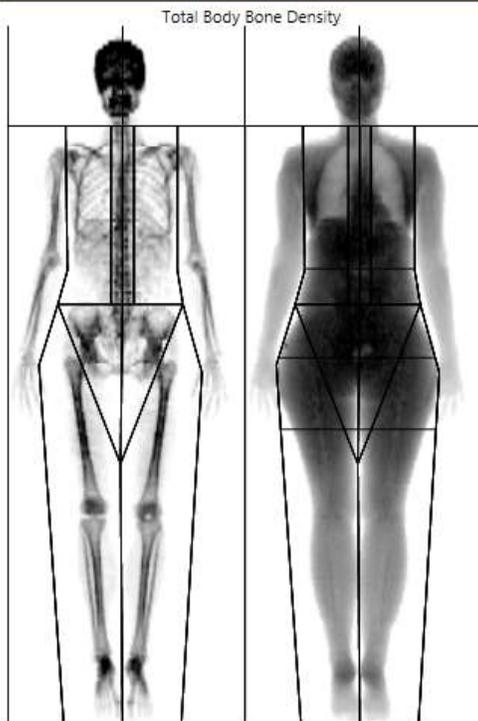
## BODY COMPOSITION

Region	Tissue <sup>1</sup> (%Fat)	Region (%Fat)	Tissue <sup>1</sup> (g)	Fat <sup>1</sup> (g)	Lean <sup>1</sup> (g)	BMC (g)	Total Mass (kg)
Arms	32.3	30.6	5,479	1,769	3,711	304	5.8
Legs	38.6	36.7	18,304	7,062	11,243	912	19.2
Trunk	31.1	30.1	24,875	7,741	17,134	818	25.7
Android	28.3	27.8	3,412	964	2,448	58	3.5
Gynoid	42.5	41.2	8,230	3,495	4,735	243	8.5
Total	33.0	31.5	52,017	17,167	34,849	2,558	54.6

## Integrative Health Technologies, Inc

5170 Broadway Ste 5  
San Antonio Texas, 78209

<b>Patient:</b>		<b>Facility ID:</b>	
<b>Birth Date:</b>	51.7 years	<b>Referring Physician:</b>	42
<b>Height / Weight:</b>	64.5 in. 118.4 lbs.	<b>Measured:</b>	9/26/2016 6:05:02 PM (13.60)
<b>Sex / Ethnic:</b>	Female White	<b>Analyzed:</b>	9/26/2016 6:05:03 PM (13.60)



Region	BMD <sup>1</sup> (g/cm <sup>2</sup> )	Young-Adult <sup>2</sup> T-score	Age-Matched <sup>3</sup> Z-score
Head	1.983	-	-
Arms	0.688	-	-
Legs	0.976	-	-
Trunk	0.779	-	-
Ribs	0.614	-	-
Pelvis	0.890	-	-
Spine	0.890	-	-
Total	0.957	-2.1	-1.2

## Atch 6. How Clinical Research Studies Benefit Patients

**Source Newsroom:** [Penn State Milton S. Hershey Medical Center](#)

Newswise — Clinical research studies are the reason medical care has improved leaps and bounds in the past few decades. Without these carefully-designed tests for new drugs, procedures or devices, treatments for diseases would not progress. These studies should be viewed as opportunities, although some people may view them negatively. "We need to change the view from researching on people to providing opportunities for people to participate in research," said [Dr. Neal Thomas](#), associate dean of clinical research at [Penn State College of Medicine](#). "Clinical research is necessary to advance medical care and is all about trying to further discoveries to find the best cure for a diseases." Here is what the public should know about clinical studies:

**Volunteers do not have to have a specific disease.** "You don't have to be sick to be in a clinical research study," said Terry Novchich, director of [Penn State Hershey's Clinical Trials Office](#). "We look for healthy volunteers for various studies depending on where we are in the development stage of that drug." For example, Novchich said a new drug may be given to healthy volunteers before it's given to individuals who have that particular disease to test their reactions, or someone healthy could be studied to compare to someone with a disease.

**Clinical studies offer crucial access for patients to cutting edge research.** In addition to providing scientists with information, clinical research studies often allow patients at academic medical centers like Penn State Hershey access to new and developing therapies that are not otherwise available. "A small percentage of the patients in the United States are treated at places like Penn State Hershey," Thomas said. "A lot of things that we do here are not offered at places that are not academic and don't have an active research program."

**Not all studies are the same.** Sometimes studies involve a medication, but others involve a device or new therapy. Some may be merely observational. "We do a lot of research here where the patient never receives anything," Thomas said. "They either just give information or they give samples of tissue or blood that allow scientists to help discover why things happen and then try to target therapies to that specific reason."

A lot of the research studies conducted at the college are not trials at all but studies that lead to discovery.

**There's a reason for the experiments.** People may fear they or their loved one will be "experimented on." Novchich and Thomas often hear potential study participants or their parents say they don't want to be a 'guinea pig.' "Part of our job is to explain that it's not experimenting on someone just to experiment. It really is trying to find the best possible treatment for their specific disease," Thomas said. At a teaching hospital, each case is looked at as a learning opportunity to advance treatment and care for the next patient. "A lot of people say even if this won't help my child, if it could help the next generation of children that come through with this problem, then it's worth it."

**Safety of participants is paramount.** According to Novchich, an independent institutional review board (IRB) ensures human subject protection during all studies. Patients always must consent to being part of a study, a process that is monitored locally by the Penn State Hershey IRB and overseen by federal regulations. The potential risks and the benefits are outlined for each volunteer during a comprehensive consent process by members of the study team prior to participating in the research study. Additionally, before a drug can be tested on humans, it often goes through years of development and any studies have to be approved by the Food and Drug Administration. "They can be assured that the research is being done to answer an important scientific question and not being done just because we want to do research," Thomas said. "The overarching goal is to improve the care of the patients that we treat, whether that's the individual patient who is recruited for the research study or future patients with the same disease process."