SUBJECTS' INFORMED CONSENT FORM

STUDY TITLE: A Pragmatic "Real-World" Study Comparing the Success or Failure of an On-going Weight Loss Plan Using the Body Mass Index (BMI) Versus a Novel Body Composition Improvement Index (BCI) and 30- and 60-Day Changes in Blood Chemistries and Self-Reported Quality of Life.

IRB PROTOCO: # 2016/09/19

SPONSOR: **Mannatech Inc., 600 S Royal Lane, Suite 200, *Coppell, TX* 75019.**

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SITE(S)**: Integrative Health Technologies, Inc., 5170 Broadway, San Antonio, Texas 78209**
STUDY-RELATED PHONE NUMBER(S):
Gilbert R. Kaats, Ph.D., 210-824-4200
Mike Gale, (Study Coordinator): 210-824-4200, 210-275-9173 (24 hours)

Purpose of this study.

While double-blinded placebo-controlled studies are considered the "gold standard" for conducting clinical trials, they often involve the creation of artificial conditions that are unlike the "real-world" conditions under which the product will be used and enrollment of subjects who differ from consumers who are most likely to use the product that is being tested. For example, in the "real-world", people must purchase the product being studied and would not do so if they had a 50-50 chance of receiving an inactive placebo. This study will examine 30- and 60-day body composition changes in members of a network marketing company (Mannatech, Inc.) who are currently participating in a weight loss plan.

The research study design and methods.

Enrollment in this study is limited to Mannatech members. Study participants will be asked to complete baseline, 30- and 60-day tests of: (1) body composition (fat, lean and bone) as measured by DEXA scans, (2) body measurements, (3) blood chemistries, and (4) self-reported quality of life. Comparisons will be made between the results of this group in which you will be participating with a control group in which free-living subjects will take the same tests, but are free to do whatever they wish between tests. At the end of the study period, subjects in both groups will receive comprehensive and reader-friendly reports of their DEXA and blood tests. Upon validation of each set of the four tests, you will be paid the following fees: Baseline-$50, 30-day-$75, and 60-day $100 for a total fee of $225 providing all three tests are taken in a timely manner (within 5 working days of due date).

Sequential Activities for Study Subjects:

Review the on-line or printed information contained in the Informed Consent and the tests and forms you will be required to complete if you choose to participate. Call the Research Center (210-824-4200) to clarify any information on these form that is not clear so you can sign the forms before coming to, or immediately upon arrival, at the Research Center. If you choose to participate, please wear loose-fitting clothing (preferably exercise or workout

attire) and allow thirty minutes to complete the DEXA test. Please be on time since we will have subjects continually scheduled before and after you. The sequence of the activities in which you will be involved are listed below.

1. **Informed Consent. Upon arrival, you will be asked to sign or turn in the Informed Consent you read on-line or picked up previously. You will be provided with a copy of your consent form.**
2. **QOL. Complete or hand in the computerized *Quality of Life Inventory* (QOL) (see Atch. 1 for a copy of the QOL.)**
3. **Blood Test. After fasting for 10 or more hours, have your blood drawn at a Quest Lab of your choosing. You will be provided with a list of Quest lab locations. A requisition in your name will have been filed in Quest's computer system. All you will need is a photo ID. You may call the lab of your choice and make an appointment for a testing time which will reduce waiting time. (See Atch. 2 for a description of the blood chemistries that will be measured.)**
4. **Hgt. & Wgt. Obtain a scale weight and a height measurement at the Research Center.**
5. **DEXA test. Complete your baseline DEXA scan. Before completing the DEXA test, you will be asked to remove your shoes, jewelry, and any metal objects. (See Atch. 3 for DEXA details)**
6. **Ankle-Brachial Blood Pressure Measurements (See Atch. 4 for details)**
7. **Body Measurements. You will be provided with instructions on how to complete measurements of your hips, waist, arms and thighs.**
8. **Lean Tracker caliper test. You will be given instructions on how to complete these measurements. (See Atch. 5 for instructions on how to take the test.)**
9. **You will be asked to complete these measurements at the Research Center in the privacy of a testing room.**
10. **Pedometer. Upon completion of the beginning tests, you will be provided with a research-quality pedometer for tracking your daily steps if you do not have an alternative devise for recording daily step totals.**
11. **Test Fees. As soon as we receive verification that you have completed all baseline tests, you will be paid a $50 testing fee. As soon as we receive verification that you have completed the 30-day tests, you will be paid a $75 testing fee. As soon as we receive verification that you have completed the 60-day tests, you will be paid a $100 testing fee. ($225 total).**
12. **TruHealth Products. Since this is a "real world" study you will be required to purchase and follow the Tru-Health system for the 60 days of the study. You will receive complete details of how and when to take the products and supplement facts for each product.**
13. **Test Reports. At the end of the study, you will also receive a comprehensive reader-friendly test report of the DEXA, ankle-brachial blood pressure and the blood tests you have taken.**

Benefits of completing study requirements:

- **You will receive three DEXA Body Composition Test Reports (total value of ~$450) and three blood chemistry test reports--a total value of ~$1,750. A unique value of repeated tests is that it will confirm the validity of your test scores.**
- **You can receive $25, $75 and $100 (total of $225) payments for taking the tests.**
- **You may be entitled to participate in future studies.**
- **Your participation will provide the benefits of participating in a clinical trial (See Atch. 6)**

In order to participate, you must:

- **be an English-speaking male or female at least 18 years of age;**
- **agree to follow the requirements of the study as set forth in this Informed Consent**
- **be participating in the Tru-Health Program**

You cannot participate if you:

- **do not speak English**
- **are under 18 years of age**
- **are pregnant or nursing and you will be excluded from the study if you become pregnant during the study**
- **your physician recommends against participation.**

<u>Study Procedures: A Checklist for Participation</u>. 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 in order to ensure you understand 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 and I understand what is expected of me.
3._____ I acknowledge that it is recommended that I 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. _____ I will incur no financial costs for participation in this study.
6. _____I will complete all required tests described above.
7. _____I understand that I can receive up to $225 for completing the three tests on a timely basis.

<u>Participant Time Involved</u>: The total time required for taking the three test batteries and forms is approximately two hours and 30 minutes.

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.

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:

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 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 terminate your involvement in 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 study, tests, or 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 your physician or healthcare provider without penalty. 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. The Sponsor's signature of this Consent Form is the Sponsor's agreement to provide all services, test results, and payments listed in this form.

HIPAA Authorization (Permission) to Use Protected Health Information (PHI) for Research

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.
Researchers would like to use your protected health information for research. The elements of protected health information as defined by HIPAA are:

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
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URL)
- Internet Protocol (IP) addresses
- Biometric identifiers, including finger and voice prints
- Full face photos and any comparable images
- Any other unique identifying number, characteristic, or code

2. **What protected health information do the researchers want to use?** The researchers want to use the results of the tests that you will complete in conjunction with participation in this study. Personal identifiers will be removed from your test results which will not be released to anyone or any agency without your written permission.
    - information about other medical conditions that may affect your participation;
    - DEXA x-rays;
    - short-term information about your general health status and,
    - data derived from blood samples that will be collected from you.

No informed consent will be shared with anyone without your written consent.
3. Why do the researchers want my protected health information? The researchers will collect your protected health information and use it if you enter this research study.

4. Who will be able to use my protected health information? The researchers will use your health information for research. All names and personal identifiers will be removed from any forms or tests you complete as part of this research. Your personal data will not be provided to the Sponsor or anyone else without your written permission.

5. How will information about me be kept private? The researchers will keep all patient information private to the extent possible, even though the researchers are not required to follow the federal privacy laws. Only researchers working with the study will have access to your information. The researcher will not release personal health information about you to others without your written permission**.**

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.

Contact Name:	Gilbert R Kaats, PhD
Contact Address:	5170 Broadway San Antonio, TX 78209
Contact Phone and FAX:	**210-824-4200 FAX:210-390-6142**

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 the researcher. The researchers will provide you with test reports of all tests you complete during the study,

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.

TITLE: ***A Pragmatic "Real-World" Study Comparing the Success or Failure of an On-going Weight Loss Plan Using the Body Mass Index (BMI) Versus a Novel Body Composition Improvement Index (BCI) and 30- and 60-Day Changes in Blood Chemistries and Self-Reported Quality of Life.***

THE NOTICE OF PRIVACY PRACTICES TELLS YOU HOW INTEGRATIVE HEALTH TECHNOLOGIES USES AND DISCLOSES INFORMATION ABOUT YOU. WE ARE REQUIRED TO GIVE YOU A NOTICE OF OUR PRIVACY PRACTICES FOR THE INFORMATION WE COLLECT AND KEEP ABOUT YOU.

I, (PRINT NAME) _____HAVE BEEN GIVEN A COPY OF INTEGRATIVE HEALTH TECHNOLOGIES, INC.'S NOTICE OF PRIVACY PRACTICES (HIPAA)

_____ _____

_____ _____

Mailing Address, city and state

_____

Primary E-mail Address and Telephone number

_____

Signature of Participant **Date**

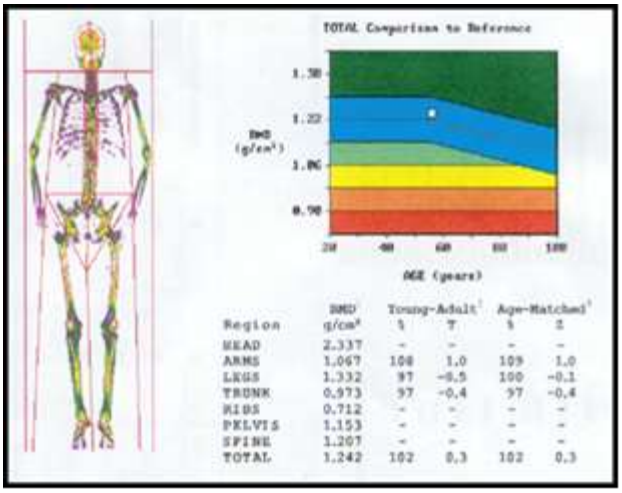
Attachment 1: Self-reported Quality of Life questionnaire

Quality of Life Inventory (QOL)								
Please report problems occuring over the last 30 days.								
0=NOT a problem 1=a MINOR problem 2=a MAJOR problem 3=a SEVERE problem								
1	Headaches	⓪①②③	30	Feeling weak	⓪①②③	59	Sleepy throughout the day	⓪①②③
2	Irritable bowel syndrome	⓪①②③	31	Eating too rapidly	⓪①②③	60	Difficulty in making decisions	⓪①②③
3	Arthritis	⓪①②③	32	Eating after being full	⓪①②③	61	Feeling restless	⓪①②③
4	Premenstrual syndrome	⓪①②③	33	Embarrassed about overeating	⓪①②③	62	Getting more tired than usual	⓪①②③
5	Recurring sinus infections	⓪①②③	34	Depressed over eating habits	⓪①②③	63	Blaming myself too often	⓪①②③
6	Tension fatigue syndrome	⓪①②③	35	Depressed about my weight	⓪①②③	64	Causing problems for others	⓪①②③
7	Recurrent anxiety	⓪①②③	36	Difficult to stop eating	⓪①②③	65	Worrying about my faults	⓪①②③
8	Recurrent depression	⓪①②③	37	Worrying about the future	⓪①②③	66	Wondering if life is worth living	⓪①②③
9	Insomnia	⓪①②③	38	Unable to concentrate	⓪①②③	67	Suicidal thoughts and worries	⓪①②③
10	Low self esteem	⓪①②③	39	Forgetfulness	⓪①②③	68	Decreasing interest in people	⓪①②③
11	Binge eating	⓪①②③	40	Bad temper or quick to anger	⓪①②③	69	Decreasing interest in activities	⓪①②③
12	Chronic tension	⓪①②③	41	Indigestion	⓪①②③	70	Difficulty in sitting/standing still	⓪①②③
13	Lack of energy	⓪①②③	42	Diabetes	⓪①②③	71	Often fidgety	⓪①②③
14	Food allergies	⓪①②③	43	Vomiting	⓪①②③	72	More tired than usual	⓪①②③
15	Feeling under stress	⓪①②③	44	Heartburn	⓪①②③	73	Generalized depression	⓪①②③
16	Cancer	⓪①②③	45	Esophageal reflux	⓪①②③	74	Difficulty in finishing activities	⓪①②③
17	Prostate problems	⓪①②③	46	Control over my appetite	⓪①②③	75	Feeling sad too much of the time	⓪①②③
18	Overeating	⓪①②③	47	Ability to relax	⓪①②③	76	Dieting too often	⓪①②③
19	Stomach pain	⓪①②③	48	Heart disease	⓪①②③	77	Difficulty in staying with a diet	⓪①②③
20	Back pain	⓪①②③	49	Fibromyalgia	⓪①②③	78	Difficulty in getting up in the morning	⓪①②③
21	Pain in arms, legs, or joints	⓪①②③	50	Difficulty in falling asleep	⓪①②③	79	Eating too much between meals	⓪①②③
22	Menstrual pain or problems	⓪①②③	51	Awakening during the night	⓪①②③	80	Eating too much during meals	⓪①②③
23	Chest pain	⓪①②③	52	Feeling sad	⓪①②③	81	Getting tired too often	⓪①②③
24	Dizziness	⓪①②③	53	Waking up too early	⓪①②③	82	Preoccupied with gloomy thoughts	⓪①②③
25	Diarrhea	⓪①②③	54	Sleeping too much	⓪①②③	83	Thinking too much about death	⓪①②③
26	Irregular heartbeat	⓪①②③	55	Unintentional weight gain	⓪①②③	84	Slowing down of my thinking	⓪①②③
27	Shortness of breath	⓪①②③	56	Unintentional weight loss	⓪①②③	85	Unhappy too much of the time	⓪①②③
28	Constipation	⓪①②③	57	Inability to concentrate	⓪①②③	86	Difficult to stop eating once I start	⓪①②③
29	Stomach gas or indigestion	⓪①②③	58	Satisfied with my life	⓪①②③			

Attachment 2: 45-measure blood chemistry measurements

The 45-Measurement Blood Test					
1	CHOLESTEROL, TOTAL	16	ALKALINE PHOSPHATASE	31	LYMPHOCYTES
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, TOTAL	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, TOTAL
10	ABSOLUTE EOSINOPHILS	25	CREATININE	40	RDW
11	ABSOLUTE LYMPHOCYTES	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	HEMATOCRIT	44	UREA NITROGEN (BUN)
15	ALBUMIN/GLOBULIN RATI	30	HEMOBLOBIN	45	WHITE BLOOD CELL COUNT

Attachment 3: DEXA Test



ANALYSIS OF YOUR FAT-FREE MASS AND BODY FAT		
1	Since you took the test fully dressed, we estimated nude weight was	
2	Using this body weight, DEXA measured your Fat-Free or Lean Mass (mostly muscle) is	
3	Subtracting your lean wgt (#2) from your total wgt (#1) means your body fat weighs:	
4	Therefore, the percentage of your total body weight that is adipose or fat mass is	
5	The average % fat for maless of all ages is	
6	Compared to maless of all ages, your % body fat is higher than ____% of maless of all ages	
7	The average % fat for maless of your age is	
8	Compared to maless of your age, your % body fat is higher than ____% of maless of your age	
9	To avoid risk factors from excess body fat, a males's % fat should not exceed	
10	If your % fat (#4) is less than %, you have a "healthy" fat %. If it is above %, you should lose this many lbs of fat without losing any of your fat-free mass (#2)	
11	If you lose the fat in #10 and maintain your lean (#2) , your "healthy" goal weight is	
12	A "Fit" % body fat for all maless is	
13	If you maintain your Fat-free Mass and lose only fat, a personalized "fit goal weight" for you will be	
14	Central or mid-section fat is the most unhealthy fat to have. Our best estimate of the % of fat in your mid-section is	
15	Our best estimate of your resting metabolism is that you burn this many calories a day at rest without moving	
16	Our best estimate of how many steps or step equivalents you take to burn a single calorie is	

What is a Bone Density Scan (DEXA)?

The following information has been reviewed by a physician with expertise in DEXA testing and was further reviewed by committees from the American College of Radiology (ACR) and the Radiological Society of North America (RSNA) by physicians with expertise in several radiologic areas.

Bone density scanning, also called dual-energy x-ray absorptiometry (DXA) or bone densitometry, is an enhanced form of x-ray technology that is used to measure bone loss. DXA is today's established standard for measuring bone mineral density (BMD). An x-ray (radiograph) is a noninvasive medical test that helps physicians diagnose and treat medical conditions. Imaging with x-rays involves exposing a part of the body to a small dose of ionizing radiation to produce pictures of the inside of the body. X-rays are the oldest and most frequently used form of medical imaging.

DXA is most often performed on the lower spine and hips. **In children and some adults, the whole body is sometimes scanned.** Peripheral devices that use x-ray or ultrasound are sometimes used to screen for low bone mass. In some

communities, a CT scan with special software can also be used to diagnose or monitor low bone mass (QCT). This is accurate but less commonly used than DXA scanning.

What are some common uses of the procedure?

DXA is most often used to diagnose osteoporosis, a condition that often affects women after menopause but may also be found in men. Osteoporosis involves a gradual loss of calcium, as well as structural changes, causing the bones to become thinner, more fragile and more likely to break. DXA is also effective in tracking the effects of treatment for osteoporosis and other conditions that cause bone loss.

The DXA test can also assess an individual's risk for developing fractures. The risk of fracture is affected by age, body weight, history of prior fracture, family history of osteoporotic fractures and life style issues such as cigarette smoking and excessive alcohol consumption. These factors are taken into consideration when deciding if a patient needs therapy.

Bone density testing is strongly recommended if you:

- are a post-menopausal woman and not taking estrogen.
- have a personal or maternal history of hip fracture or smoking.
- are a post-menopausal woman who is tall (over 5 feet 7 in) or thin (less than 125 pounds).
- are a man with clinical conditions associated with bone loss.
- use medications that are known to cause bone loss, including corticosteroids such as Prednisone, various anti-seizure medications such as Dilantin and certain barbiturates, or high-dose thyroid replacement drugs.
- have type 1 (formerly called juvenile or insulin-dependent) diabetes, liver disease, kidney disease or a family history of osteoporosis.
- have high bone turnover, which shows up in the form of excessive collagen in urine
- have a thyroid condition, such as hyperthyroidism.
- have a parathyroid condition, such as hyperparathyroidism.
- have experienced a fracture after only mild trauma.
- have had x-ray evidence of vertebral fracture or other signs of osteoporosis.

How should I prepare?

On the day of the exam you may eat normally. You should not take calcium supplements for at least 24 hours before your exam. You should wear loose, comfortable clothing, avoiding garments that have zippers, belts or buttons made of metal. Objects such as keys or wallets that would be in the area being scanned should be removed.

You may be asked to remove some or all of your clothes and to wear a gown during the exam. You may also be asked to remove jewelry, eye glasses and any metal objects or clothing that might interfere with the x-ray images.

Inform your physician if you recently had a barium examination or have been injected with a contrast material for a computed tomography (CT) scan or radioisotope scan. You may have to wait 10 to 14 days before undergoing a DXA test.

Women should always inform their physician or x-ray technologist if there is any possibility that they are pregnant. Many imaging tests are not performed during pregnancy so as not to expose the fetus to radiation. If an x-ray is necessary, precautions will be taken to minimize radiation exposure to the baby.

How does the procedure work?

The DXA machine sends a thin, invisible beam of low-dose x-rays with two distinct energy peaks through the bones being examined. One peak is absorbed mainly by soft tissue and the other by bone. The soft tissue amount can be subtracted from the total and what remains is a patient's bone mineral density. DXA machines feature special software that compute and display the bone density measurements on a computer monitor.

How is the procedure performed?

This examination is usually done on an outpatient basis. In the Central DXA examination, which measures bone density in the hip and spine, the patient lies on a padded table. An x-ray generator is located below the patient and an imaging device, or detector, is positioned above.

What are the benefits?

- DXA bone densitometry is a simple, quick and noninvasive procedure.
- No anesthesia is required.
- The amount of radiation used is extremely small—less than one-tenth the dose of a standard chest x-ray, and less than a day's exposure to natural radiation.
- DXA bone density testing is the most accurate method available for the diagnosis of osteoporosis and is also considered an accurate estimator of fracture risk.
- DXA equipment is widely available making DXA bone densitometry testing convenient for patients and physicians alike.
- No radiation remains in a patient's body after an x-ray examination.
- X-rays usually have no side effects in the diagnostic range

What are the Risks?

There is always a slight chance of cancer from excessive exposure to radiation. However, the benefit of an accurate diagnosis far outweighs the risk. The effective radiation dose from this procedure is about 0.01 mSv, which is about the same as the average person receives from background radiation in one day. Women should always inform their physician or x-ray technologist if there is any possibility that they are pregnant. No complications are expected with the DXA procedure.

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.

Attachment 4: Ankle-brachial blood pressure index (ABI) and resting heart rate

The ankle brachial pressure index (ABPI is obtained by taking a resting blood pressure measurements of the subject's upper arm and just above the ankle. The ABI is the ratio of the blood pressure in the ankle compared to the blood pressure in the arms. The ABI is calculated by dividing the systolic blood pressure at the ankle by the systolic blood pressures in the arm to provide a measure of the health of the blood circulatory system. To enhance test-retest reliability, the ABPI will be obtained while the subject is still lying down on the scanning table after the 15-20 minutes needed to complete the DEXA.

Attachment 5: Self-administered Calipers

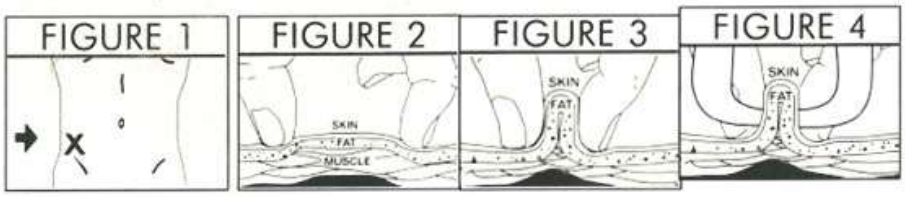
The ***Lean Tracker*** **Body Fat Estimator** Since the majority of fat in the body is located directly under the skin, you can estimate % body fat with a "skinfold" or "pinch an inch" method. The *Lean Tracker* has been shown to be a reasonable estimate of body fat. But remember, it is an estimate, not a measure.

Step 1 The site you will use for skinfold measurement is the suprailliac (approx one inch above the right hipbone, see figure 1 below).

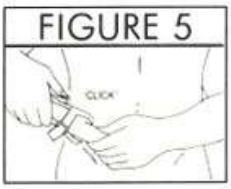
Step 2 While standing, firmly pinch the suprailliac skinfold between your left thumb and forefinger as shown in figures 2 & 3.

Step 3 Place the jaws of the *Lean Tracker* over the skinfold, continuing to hold the skinfold with the left hand as in Figure 4 below.

Step 4. Press with the thumb where indicated on the Personal Body Fat Tester until you feel a slight click..



Step 5. The slide member will automatically stop at the correct measurement, see figure 5. After reading your measurement, return the slide member to the far right starting position. Repeat three times and use the average as your measurement



Attachment 6: How Clinical Research Studies Benefit Subjects

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."