

## SUPPLEMENTAL SUBJECTS' INFORMED CONSENT

**TITLE: *A Comparison Between Body Fat and Fat-Free Mass Assessed by Multiple Bio-impedance Assessments (BIA) Assessments (BIA) & Total Body Dual Energy Absorptiometry*"**  
**(DEXA—IRB Protocol #2016/05/11)**

**SPONSOR:** Mannatech Incorporated, 600 South Royal Lane, Coppell, TX 75019

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

<sup>a</sup>Integrative Health Technologies, Inc. San Antonio, TX, 78209

<sup>b</sup>Professor of Medicine, Departments of Biochemistry, Physiology, Medicine and Pathology, Georgetown University Medical Center, Washington, D.C. 20057

<sup>c</sup>Women's Total Healthcare, 315 East Mulberry Street, Angleton, TX 77515

**SITE(S):** Integrative Health Technologies, Inc., 5170 Broadway, Suite 5, 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)

**The Purpose of this study.** This study is designed to examine short-term changes in the test data we obtained from you in the previous DEXA/BIA study and to examine interrelationships between these tests and the 43-chemistry blood test shown in the attached Informed Consent.

**Participation Requirements:** In this extension you will be asked to complete a test battery at baseline, 30 days and 60 days from baseline containing the same DEXA test, Quality of Life questionnaire, physical measurements you previously completed. However, in this extension you will be asked to also complete the 45-blood chemistry test shown below. No- bio-impedance test that were taken in Phase 1 will be taken in this study.

### **Sequential Activities for Study Subjects:**

1. **On-Line Information.** Review the on-line Informed Consent and the Quality of Life (QOL) inventory that you will be required to complete if you volunteer to participate. Samples of test reports that you will receive are also available on this website. Call the Research Center (210-824-4200) to clarify any information on these forms that is not clear.
2. **Visit the Research Center.** If you are willing to volunteer, complete the Informed Consent and QOL and make an appointment to visit the Research Center to schedule testing and turn in the completed Informed Consent and QOL. You will be provided with a copy of the jointly signed Informed Consent's signature page.
3. **Required tests.** You will be asked to complete three sets of the test battery described below—one at baseline, 30-days and 60-days as described in the procedures below.
  - a. **DEXA Test.** This is the same test you completed in the first phase. Please refer to Atch. 1 for the most current information on the DEXA test. Before completing the test, the same procedure will be followed asking you to remove your shoes, jewelry, and any metal objects. When taking the test, please wear loose-fitting clothing (preferably exercise or workout attire) and allow twenty minutes to complete it. Please be on time since we will have subjects continually scheduled before and after you.
  - b. **Quality of Life Inventory (QOL)** This is the same test in took in the first phase.

- c. **Body measurements.** These are some of the same measurements you completed in the first test only this time it will be limited to hips, waist, and thighs and completed by same-sex technician. You may still continue in the study if you object to having these measurements taken.
- d. **Caliper Measurements (Atch 1)** You will be provided with a plastic caliper and asked to take the caliper measurement as described in Atch 1.
- e. **Blood tests. (Atch 2)** The blood chemistries that will be measured are shown in Atch 2. Pick up a requisition to have your blood drawn at a Quest Lab location of your choosing. Be sure to fast for at least 10 hours before taking the test. Taking increased amounts of water will make it easier for the technician to find your veins. Also, keeping the arm warm where the blood sample will be obtained can also make finding your veins easier. It typically takes 2-3 days for receipt of your blood test results. Please indicate below how you want to be notified when we receive all of your test results:

**Call or email to:** \_\_\_\_\_

- 4. **\$225 testing fees.** You will be paid the following fees for taking the tests: \$50 for the baseline tests, \$75 for the 30-day tests and \$100 for the 60-day tests (\$225 total). These fees will be paid promptly upon receipt of each of the completed test results.
- 5. **Receiving test results.** Since these tests have medical implications, you must authorize us to email the results to you. Please indicate in the space provided how you want your results sent to you:

**Email to:** \_\_\_\_\_

**Mail to:** \_\_\_\_\_

- 6. **How to interpret your test results.** To help you better understand your DEXA results, you will be given a password-protected website providing detailed information on how to interpret your DEXA and blood chemistry reports. (These instructions are generic and will not include your personal test results.) No information will be provided on the measurements of your hips, waist, and thighs.

**Benefits of completing study requirements:**

- You will receive three DEXA Body Composition Test Reports (average value of \$125 each and three blood chemistry test reports of an average total value of \$435)—a total value of \$\$1,630 .
- You will receive a total of \$225 fees to taking the tests;
- You may be entitled to participate in future studies; and
- Your participation will provide the benefits of participating in a clinical trial as provided in the Phase 1 attachment.

**in order to participate, you must have participated in the previous phase and agree to follow the requirements of the study as set forth in this Informed Consent**

**Study Procedures: A Checklist for Participation**

1. \_\_\_\_\_ I have read this Informed Consent and met with the research coordinator and understand what is expected of me.
  
2. \_\_\_\_\_ I am willing to participate in this extension and acknowledge that upon signing this Informed consent, I will be enrolled as a participant.
  
3. \_\_\_\_\_ I will incur no financial costs in this extension.
  
4. \_\_\_\_\_ I will complete all required tests described above.
  
5. \_\_\_\_\_ I am aware that all conditions of the Informed Consent and HIPAA requirements for the first phase of this study are applicable to this extension.
  
6. \_\_\_\_\_ I agree to withdraw from the study if I am pregnant or become pregnant.

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

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

**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 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 all tests and payments for completing the 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.

NAME \_\_\_\_\_ DATE \_\_\_\_\_

ADDRESS \_\_\_\_\_ ZIP Code \_\_\_\_\_

Telephone: \_\_\_\_\_

EMAIL \_\_\_\_\_

## Atch 1. Caliper

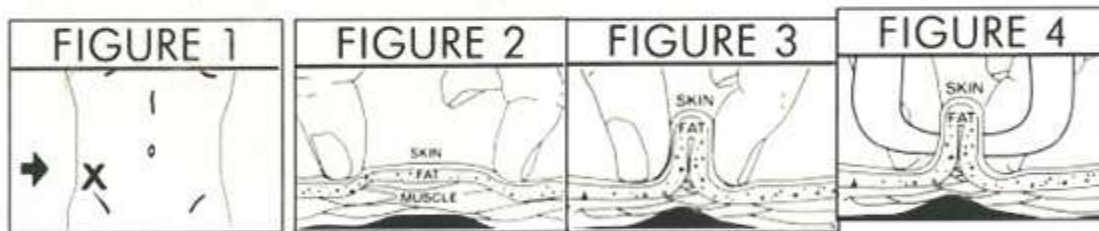
The *Lean Tracker Body Fat Estimator* Since the majority of fat in the body is located directly under the skin, you can estimate % body fat with a "skinfold" or "pinch an inch" method. The *Lean Tracker* has been shown to be a reasonable estimate of body fat. But remember, it is an estimate, not a measure.

**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



## Atch 2. The Blood Chemistry Panel

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