SUBJECTS' INFORMED CONSENT

TITLE: ***A Comparison Between Body Fat and Fat-Free Mass as Assessed By Multiple Bio-impedance Assessments (BIA) and Total Body Dual Energy Absorptiometry (DEXA):***
RB PROTOCOL #: 2016/05/10

SPONSOR: Jawon Medical, a South Korean corporation with its principal offices located at 8F Bando B/D, 26,Gomurae-ro 10-gil, Seocho-gu, Seoul, Korea, 06593

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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 Coordinator): 210-824-4200, 210-275-9173 (24 hours)

The Purpose of this study. The DEXA test of body composition (Body Fat, Fat-free mass and Bone Density) is generally consider the "gold standard" for the measurement of body composition. However, due to its limitation of availability, expense, space requirements and restrictions on third-party payments, alternative measures of body composition have been sought. One measure that has most frequently been used is Bio-Impedance Assessments (BIA). However, while BIA can provide an "estimate" of DEXA-measurements, it has yet to be considered a comparable measurement. This study seeks to reduce the amount of error between DEXA and BIA by developing a statistical equation from data derived from the simultaneous completion of DEXA tests and six different BIA technologies.

If you participate, you will be required to complete the following activities approximately in the order listed:
Review the on-line or printed information contained in the Informed Consent that you will be asked to follow if you choose to participate in the study. Call the Research Center (210-824-4200) to clarify any information on the Informed Consent Form that is not clear so you can sign the Form immediately upon arrival at the Research Center. Please wear loose-fitting clothing (preferably zipper-less exercise or workout attire) and allow about an hour and thirty minutes to complete the study. Please be on time since we will have subjects continually scheduled before and after you.

1. Fast for 2 hours prior to arrival and refrain from exercising during this 2-hour period.
2. Upon arrival, you will be asked to sign this Informed Consent.
3. Complete the computerized *Quality of Life Inventory* in testing room #2 **(**A copy of the form is at **Atch 1)**.
4. Obtain measurements of your scale weight and height without shoes in office #5.
5. Go out to the testing van to complete the DEXA test **(**Extensive Information on the DEXA is at **Atch 2)**.
6. You will be asked to remove your shoes, socks, jewelry, and all metal objects.
7. After completing the DEXA, you will be asked to complete four Bio Impedance measurements while still on the testing table **(**Information on the Bio Impedance unit is at **Atch 3)**.
8. Go to room #3 and a technician will measure the circumference of your hips, waist, neck, both arms and both thighs. A female or a spouse must be present when measuring females.
9. Upon completion of these measurements, you will then be asked to remove your shoes and socks and complete the bio-impedance measurements.
10. The Technician will then ask you to complete a short critique form and provide you with a $50.00 cash payment for taking the above tests. You will be provided with this fee even if you choose not to take one or more of the tests.
11. You must authorize the technician to email your DEXA test results. Without this authorization, we will mail results to you within 48 hours.
12. A sample test report is on-line to help you better understand your DEXA results, you will be given a password-protected website of a voice-over power-point presentation providing detailed information on how to interpret your DEXA Report. These instructions are generic and will not include your specific test results. No information will be provided on the Bio Impedance test results.

Summary of Requirements: If you choose to enroll in the study, you agree to complete the DEXA and BIA tests described above.

Risks of participation: There are no known risks associated with taking the bio-impedance measures (**Atch. 4**). Risks associated with taking the DEXA test are minimal and are described in **Atch. 2**.

Benefits of participation:

- □ You will receive a DEXA Body Composition Test Report with an average value of $200 **(Atch 1)**;
- □ You will receive a participation $50 fee;
- □ You may be entitled to participate in future studies; and
- □ Your participation will contribute to medical science as described in **Atch 4**

Eligibility Requirements

In order to participate, you must:

- be an English-speaking male or female from 18 to 60 years of age;
- agree to follow the requirements of the study as set forth in this Informed Consent;
- refrain from eating two hours before taking the tests;
- do not take caffeinated or diuretic beverages two hours before taking the tests; and
- wear light clothes, preferably exercise or workout clothes without zippers.

You cannot participate if:

- you do not speak English
- you have a pacemaker or any other medical implants
- you are under 18 years of age
- you are pregnant or nursing
- your healthcare provider 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 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 to ensure I understand what will be expected of me.
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 may enroll as a participant.
5. _____ Participation in the study will be at no cost to me.
6. _____I will complete all the required tests described above.

Payments for Testing: Upon completing the tests, you will be paid $50 immediately for taking the test and allowing us to use your redacted (without personal identifiers) data exclusively for research purposes.

Participant Time Involved: The total time required for the study is approximately one hour and 30 minutes after you arrive.

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 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 an immediate payment of $50.00 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.

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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)

_____ _____

INDIVIDUAL'S SIGNATURE **DATE**

Mailing Address: _____

Primary E-mail Address_____

_____ _____ _____

Signature of Participant Date Telephone Contact