Nova Southeastern University
Institutional Review Board for Research with Human Subjects (IRB)
New Protocol Submission

Center Rep:	**To be completed by IRB Office**
Date Sent to IRB:	**Protocol Number:**

Instructions: In order to comply with federal regulations and with the university's IRB guidelines, the Principal Investigator (PI) is required to complete all of the following items. After completing, submit this document and all consent forms and research instruments (questionnaires, interviews, etc.) to the appropriate IRB College/Center Representative. You can find your college/center representatives using the following link: http://www.nova.edu/irb/membership.html.

- If your study qualifies for center level exemption from further review, the Center Representative will exempt your study, provide you with a memo to that regard, and give you copies of the stamped, approved consent/assent form(s), if applicable. The Center Representative will log your study into the IRB database and forward a copy of the complete submission to the IRB office.
- If your study appears to qualify for expedited review, then once the Center Representative believes the submission is complete, the Center Representative will log your study into the IRB database and forward **ONE** complete submission packet to the IRB office for review.
- If full review is required, the Center Representative will log the study into the IRB database and will provide the PI with instructions for submitting 23 stapled or rubber banded copies (AND 1 unstapled original) of the submission and all supporting materials (research protocol, consent/assent forms, letters of authorization, etc.) to IRB. Please note: ONLY ONE copy of all research instruments (tests instruments, interview protocols, etc.) needs to be submitted. The completed package must be received by the IRB by the last business day of the month prior to the next scheduled IRB meeting. Because mail, including express delivery, takes at least a day to be delivered within the university, please make allowance for this in your planning. Incomplete submissions will delay review by the IRB. The IRB reserves the right to postpone review of protocols at convened meetings due to needed revisions.

Use a word processor to complete this form. You do not need to be concerned about where page breaks fall. You are to complete all **BLUE** sections. Be sure that all pages, including any appendices or attachments, except for consent/assent forms and advertisements, are numbered sequentially. For further information, refer to http://www.nova.edu/irb/manual/policies.html and http://www.nova.edu/irb/process.html

Do **not** approach subjects about being in the research study until you have received NSU IRB approval.

Form Version: December 2009

1. General Information

1.A. Research Project Title:

Local Tissue Water Variations Among Different Races Measured via Tissue Dielectric Constant

1.B. Insert Principal Investigator's (PI) Last Name and Date of Submission in the footer.

1.C. Brief Overview (Max 250 Words):

The purpose of this investigation is to quantitatively determine local skin tissue water (STW) via measurements of skin tissue dielectric constant (TDC) in five distinct racial groups; Asian Indians, Hispanic, Blacks, Whites, and Asians. The main purpose of these measurements is to characterize the distribution of TDC among these groups, to determine if skin variations or other differences among the groups result in significant variability in STW as determined via TDC measurements. A second purpose is to determine if local tissue water is quantifiably related to the whole body fat and water percentages as determined using whole body bioimpedance measurements. We will be assessing the TDC in three areas bilaterally; anterior chest, anterior

forearm, and posterior medial malleolus region. We will be using two probes that measure to different depths: 2.5 mm and 5.0 mm. Both will be used to assess the TDC in the subclavicular region (anterior chest wall) and the anterior forearm (antecubital fossa). Only the 2.5mm probe will be used to assess the posterior medial malleolus region. Whole body water percentage will be determined via bioimpedance measurements. All measurements will be taken with the patient in the supine position. Set-up, patient acclimatization and measurements will take approximately 30 minutes to complete. We plan to recruit 100 subjects to participate in the study consisting of 10 males and 10 females from each of the above mentioned groups. All data and consent forms will be stored in separate locked cabinets in room 1313 of the Terry building.

1.D. Principal Investigator (PI) Information

Name	Harvey N. Mayrovitz, PhD	Relationship to NSU	
Mailing Address (for Students)	N/A		
Interoffice Mail Code (for Faculty/Staff)	1-11101	Student	
Daytime Phone	954-262-1313	Faculty	**X**
Alternate Phone	N/A	Staff	
NSU Email Address	mayrovit@nova.edu	NSU Center/College/Dept	
Alternate Email Address	N/A	HPD/CMS/Physiology	
Degree/Academic Information	PhD/Professor	PI CITI Completion Date*	
		July 2008	

Please briefly describe your applicable professional, educational, employment, professional licensure, and research experience. Do NOT attach your vitae.

Currently a Professor of Physiology in the College of Medical Sciences. Over 15 years of research experience as exemplifies by the following sampling of peer reviewed research publications:

Mayrovitz HN, Sims N, Pfister S, Litwin B (2005). Foot volume estimates based on geometric algorithm in comparison to water displacement. Lymphology 2005;38(1):20-27

Mayrovitz HN, Grossclose EE, King D. (2005) No effect of 80mT permanent magnets on laser-Doppler measured blood flow response to inspiratory gasps. Bioelectric magnetic. 2005;26(4):331-335.

Mayrovitz HN.Compression Therapy. In: Wound Healing Ed. Falabella, A.F. and Kirsner, R.S. Published by Taylor and Frances, Boca Raton Florida Chapter 33 pp 409-421 isbn 0-8247-5458-1, 2005.

Mayrovitz HN, Grossclose EE. (2005). Effects of a static magnetic field of either polarity on skin microcirculation. MVR 2005:69:24-27.

Mayrovitz HN, Grossclose EE (2005). Inspiration induced vasoconstrictive responses in dominant vs. non dominant hands. Clinical Physiology Functional Imaging . 2005:25:69-74.

Mayrovitz HN, Sims N, Cross-Brown et al. (2005). Ranscutaneous oxygen tension in arms of women with unilateral postmastectomy lymphedema. Lymphology 2006;39(2) 95-103.

Mayrovitz HN, Sims N, Hill C et al. (2006) Hand volume estimates based on a geometric algorithm in comparison to water displacement. Lymphology 2006;39(2):95-103.

Mayrovitz HN (2007). Assessing local tissue edema in postmastectomy lymphedema. Lymphology 2007;40:87-94.

Mayrovitz HN, Brown-Cross D, Washington Z (2007). Skin tissue water and laser Doppler flow during a menstrual cycle. Clinical Physiology and Functional Imaging 2007;27:54-59.

Mayrovitz HN, Macdonald J, Davey S, Olson K, Washington E. (2007) Measurement decisions for clinical assessment of limb volume changes in patients with bilateral and unilateral limb edema. Physical Therapy 2007 (October) 87: (10) 1362-1368.

Mayrovitz HN. (2007). Interface pressures produced by two different types of lymphedema therapy devices. Physical Therapy (October) 87:(10) 379-1388.

Mayrovitz HN,Davey S, Shapiro E (2008). Local tissue water changes assessed by tissue dielectric constant: single measurements vs. averaging of multiple measurements. Lymphology 2008:41:186-188.
Mayrovitz HN, Davey S, Shapiro E. (2008) Local tissue water assessed by dielectric constant: anatomical site and depth dependence in women prior to breast cancer related surgery. Clinical Physiology Functional Imaging. 2008;28:337-342.
Mayrovitz HN, Davey S, Shapiro E (2009) Suitability of single tissue dielectric constant measurements to access local tissue water in normal and lymphedematous skin. Clinical Physiology and Functional Imaging 2009; (29) 23-127.
Mayrovitz HN and Soontupe LP (2009). Wound areas by computerized plainimetry of digital images: accuracy and reliability advances in skin and care 2009; 22:222-229.
Mayrovitz HN, Brown-Cross D, Mayrovitz B, Humble-Golla A. (2009) Lymphedema: Role of truncal clearance as a therapy component. Home Health Care Management & Practice 2009; 21 (5) 325-337.
Mayrovitz HN (2009). The standard of care for lymphedema: Current Concepts and Physiological Considerations

1.E. Co-Investigators (Co-I) Information (including faculty advisers)

	Co-Investigator 1	Co-Investigator 2	Co-Investigator 3
Name	Sharien L. Amarnani	Eric Pitts	Louis Michaelos
Mailing Address	2550 SW 18th Terrace Apt #1404 Fort Lauderdale, Fl 33315	709 NE 7th Street Pompano Beach, Fl 33060	6825 Lakeside Circle North Davie, Fl 33314
Contact Phone Number	407-719-3398	210-363-6822	727.460.1465
Email Address	Sa742@nova.edu	Ep434@nova.edu	Lm1217@nova.edu
Degree/Academic Information:	DO/1st Year Medical Student	DO/1st Year Medical Student	DO/1st Year Medical Student
CITI Completion Date*	06/06/10	12/14/2010	12/23/2010

Please briefly describe applicable professional, educational, employment, professional licensure, and/or research experience for all co-investigators. Do NOT attach vitae.

Sharien L. Amarnani, BS
University of South Florida, Tampa, Fl
Biology, BS
Biomedical Science, BS

Eric Pitts, BS
Virginia Polytechnic Institute & State University, Blacksburg, Va
Biochemistry, BS
Chemistry, minor
Leadership, minor

Louis Michaelos, BS
Stetson University, DeLand, Fl
Biology, BS

1.F. Research Assistant Information (if applicable)			
	Research Assistant 1	Research Assistant 2	Research Assistant 3
Name			
Mailing Address			
Phone Number			
Email Address			
CITI Completion Date*			

*NOTE: CITI must have been completed within the last 3 years. If a member of the research team is affiliated with another institution, please include a copy of that individual's training certification.

1.G. Funding Information				
Funding status	Unfunded X	Funding Applied For	Funded	
If you indicated "Funded" or "Funding Applied For," complete the following.				
Source of Funding	N/A			
Project Title (if different from above)				
Principal Investigator (if different from above)				
Type of Application	Grant	Subcontract	Contract	Fellowship
Award Amount:				

1.H. Management of Conflict of Interest

Read the conflict of interest guidelines at http://www.nova.edu/ogc/forms/ogc9906.pdf

I certify that I, as PI, have read these guidelines, and have verified that my co-investigators and research assistants also have read these guidelines. PI Initials: HNM

Do any investigators have a significant financial interest (as defined by NSU policy) in relation to this study? Yes: | No: X

If yes, please describe the nature of the conflict of interest below

If you answered yes, please be sure to include the following statement, or a similar statement, within the description section of the consent forms: "The principal investigator and/or co-investigator(s) of this research study have a significant financial interest as it relates to this study." Continue, describing the conflict in the consent/assent documents.

1.I. Dates and Phases of Study			
Proposed Start Date			
Shortly after IRB approval	X	Other (list date)	
Proposed Duration of Research (including analysis of the results)			
One year or less X	Other (describe, please note minimum annual continuing review required)		

Is this a multi-part study?

Yes	No
	X

If "Yes," please note that procedures used in later phases may affect the review status of this study. Briefly describe the later stages.

1.J. Multiple Site Information

Will the study be conducted at an NSU location?

Yes	No
X	

If "Yes," provide the location within NSU, e.g. department or clinic.

Room 1305A of College of Medical Sciences

Will the study be conducted at a non-NSU location?

Yes	No
	X

Will any of the activities be done online or via telephone (e.g., completion of surveys, delivery of instructional content)?

Yes	No
	X

If "Yes", for the Internet based activities, will these be done via a secure site?

Yes	No

If "Yes," please complete the following for the non-NSU sites.
Include these sites on the consent form in the "site information" section.

	Site 1	Site 2	Site 3
Site Name			
Address			
Phone Number			

You will need documentation of permission to conduct the research at non-NSU sites. Attach the permission letter(s) or IRB approvals to this document.

1.K. Cooperative Research

Cooperative research projects are those that involve more than one institution or when an investigator is employed at or is an agent of an institution other than NSU, (For more information, see **http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html**). Each participating institution is responsible for safeguarding the rights and welfare of human subjects and for complying with all regulations.

Does this research involve cooperative research?

Yes	No
	X

Has this proposal been submitted or will the proposal be submitted to another Institutional Review Board (or authorizing individual, entity, or ethics review board) for review?

Yes	No
	X

If "Yes," please complete for each site. Please attach documentation of approval. (Copy the section of the table and add if there are multiple sites.)			
Name of Institution			
IRB/Administrative Decision (check applicable)			
Approved ☐	Submitted (not yet approved) ☐	Not yet submitted ☐	NSU IRB approval required prior to submission ☐
Date of Review	Contact Person Phone Number	**Level of Review (if IRB Reviewed)**	
		Exempt ☐	Expedited ☐ / Full ☐

2. Subject/Participant Information

2.A. Overview of Proposed Subjects/Participants

(complete **all** that apply and provide maximum number proposed within each category):

Subject Group	Fetus in Utero/ non-viable fetuses/ abortuses	Newborns or Infants	Children (aged 2-6)	Children (age 7-12)	Adolescents (aged 13-17)	Adults (18+)	Pregnant Women	Adults with Guardians
Mark X for each proposed subject type						X		
# of Proposed Subjects*						100		

Please briefly describe your potential subjects:

Subjects will be recruited from the HPD student body and will not include students being taught or will be taught or advised by Dr. Mayrovitz or the Physiology department. Dr. Mayrovitz will not solicit participation as the Principal Investigator. All students will be recruited by word of mouth. They will be between the ages of 18-48 and will consist of both males and females. We will recruit 10 males and 10 females for each of the following racial groups: Asian-Indian, Blacks, Hispanic, Whites, Asian for a total of 100 subjects. Participants will be given a movie ticket in return for participation. If a subject decides midway not to continue he/she will still be awarded the ticket.

*By proposed subjects, the IRB means subjects who will consent to be in the study and begin the study activities.

2.B. Subject Vulnerability

Do any subjects have limited decision-making autonomy, have communication problems that would limit ability to dissent to study procedures, belong to a group that is vulnerable to coercion, or belong to a group defined by regulation as requiring greater care?	Yes ☐	No X

If you indicated "Yes", please mark with an X next to each applicable category in the column to the right and complete the remainder of this section	
Prisoners	
Pregnant Women	
Cognitive impairment or emotional problems that potentially limit decision making	
Communication impairments that may preclude communicating a decision to discontinue participation or refuse participation	
Students of the investigator or investigator's department or Advisee	
Employees of the investigator or investigator's department	

Children (minors)	
Terminally ill	

Other (specify):

N/A

If you indicated any of the above, please justify your rationale for including these subjects.

N/A

If you are using potentially vulnerable subjects as described above (infants, children, pregnant women/fetuses, terminally ill, decision-impaired, communication-impaired, students/employees, or prisoners), does the research create greater than minimal risk?	Yes	No
		X

If your subjects have a vulnerability that arises from their being students in your class or department, you will be asked for more information in Section 3.G. If the subjects have one of the other vulnerabilities, please describe proposed safeguards to protect vulnerable subjects.

N/A

If not evident from the researcher qualification information in 1.D. or 1.E., please describe the researcher(s) qualifications for working with vulnerable subjects

N/A

2.C. Study Design and Methodology

Part 1 – Purpose

Please briefly describe the **purpose** of your study. Note: Examples of study purposes are "to determine if a new reading intervention program improves 4th graders' reading scores" or "to survey patients on their perception of physical therapy services".

The purpose of this investigation is to quantitatively determine local skin tissue water (STW) via measurements of skin tissue dielectric constant (TDC) in five racial groups: (1) Asian Indians defined as persons with ancestry from the Indian Subcontinent; (2) Hispanics defined as persons with ancestors from Hispanic countries in Central or South America, Dominican Republic, Cuba, or Puerto Rico and Spain; (3) Asian defined as persons with ancestors from China, Japan, Korea, Philippines, Vietnam, Thailand, or Cambodia; (4)Blacks and (5)Whites. The main purpose of these measurements is to characterize TDC distribution among these groups to determine if skin variations or other differences among the groups result in significant variability in STW.
A second purpose is to determine if local tissue water is quantifiably related to the whole body water and fat percentages as measured using whole body bioimpedance measurements

Part 2 – Goals and Justification

Briefly elaborate on the main **goals and justification** for the study. Summarize the background, rationale, nature, and significance of the proposed research. Include a brief overview of your prior research in the area, or literature that supports the need for this study. This section should be a brief overview, and typically is not more than a few paragraphs in length. You will be asked about procedures and instruments later in the submission.

Local skin tissue water can be determined by measuring the tissue's electrical dielectric constant at any skin location. The method has been described as the Tissue Dielectric Constant (TDC) method. The TDC is an important non-invasive measure and indicator of skin tissue water and is used as an index of changes in local skin tissue water at different sites on the human body

in healthy persons, in conditions such as lymphedema, patients with post-mastectomy lymphedema, swollen extremities, and foot (1-9). TDC values so obtained have been used to characterize features of a given abnormal condition in which tissue water is of relevance and also to evaluate treatment related changes (10). Measurements in normal tissues have been used to establish a continuously developing reference data base from which judgments as to deviations from normality might be judged. However, to date most of such measurements have been made on Whites so that the extent of STW variations in individuals of different racial backgrounds is largely unknown.

In terms of structure and function of the skin, an observed reduction in susceptibility to irritation in Black and Hispanic versus white subjects has been historically attributed to reduced permeability of the stratum corneum in the Black population (11). There are also differences in skin types among (and within some) races that are characterized as type I through type VI depending mainly on the skin sensitivity to irritants and to sun burning and tanning. For example type IV skin, typical of Mediterranean Whites, has minimal sensitivity to the sun, minimally burns, and always tans to moderate brown whereas some Hispanics and some Blacks have Type V skin which is insensitive to the sun, rarely burns and tans well. Type VI skin is characteristic of darker Blacks and is insensitive to the sun, never burns, and is deeply pigmented (12). Blacks with skin type VI, generally have a lower pH and a higher transepidermal water loss (TEWL) than Whites with skin types I and II (13)**.** There are also differences among races in skin components such as the amount of melanin produced by melanocytes and the amount that is stored in keratinocytes. In addition, immunohistochemical analysis has shown that constitutive expression of Mircrophthalmia transcription factor (MITF), which is considered the master regulator of melanocyte function, was highest in Black skin. However, in Asian and White skin, MITF was detectable in amounts <50% of that found in Black skin (14). The presence of the various differences in skin features among races provides the plausible basis for the hypothesis that there are also differences in skin tissue water among racial groups. If such differences are present, then the characterization of those differences would provide useful reference values for specific racial groups. If no differences exist, then a single reference value database would be indicated. Thus, the purpose of this investigation is to quantitatively determine and compare TDC values among five different racial groups; Asian-Indian, Black, Hispanic, White, and Asian. Another important issue to be investigated is the possible relationship between local skin tissue water and whole body water and fat percentages. Although virtually nothing is known about this whole body-local tissue relationship, it is our hypothesis that persons with a greater percentage of whole body water will also have a greater TDC value at the measured skin sites and individuals with a greater whole body fat percentage values will have lower TDC values at the measured skin sites. This portion of the research is important because the findings may enhance the treatment approach for patients suffering from lymphedema and/or other diseases that result in tissue fluid retention.

Part 3 – Steps in the Research Study

In the box below, please outline in detail the **steps in the research study** in order as they will occur after consent has been secured. If there are different requirements for different groups/types of subjects within the study, please separate out the steps per group. Indicate how long the subject spends completing the different steps/procedures. Be specific about the tests given and/or treatments used, when they will occur, and their frequency.

A. Protocol and Sequence Overview

Prior to the experimental measurement visit, a co-investigator (CI) will meet with the potential subject to provide the description and goals of the study and explain the content of the Informed consent. As part of this explanation the CI will advise the potential subject that it will be necessary to avoid the application of lotions/oils at the sites where measurements will be made and in the case of female subjects that it will be necessary for her to wear a sports bra at the time of the scheduled experimental measurement visit. At this preliminary meeting any questions the subject has regarding the research study will be answered by the CI and an informed consent will be ultimately obtained. The CI will then schedule the subject for the experimental measurement session.

All study related procedures will be done in room 1305A in the Terry building at the HPD of Nova Southeastern University with two CI's present. For female subjects, one female and one male CI will be present and measurements on female subjects will be performed only by a female CI. Upon arrival the subject will be weighed on a standard floor scale and will be asked to complete a 14 question questionnaire as shown in appendix 1. The purpose of the questionnaire is to gather information that may help account for potential confounding variables related to the subject's daily habits. After completing the questionnaire the subject will remove their shoes, socks and shirt and lie supine on a padded exam table. As previously noted, all female participants will have been advised to wear a sports bra on the day of the experiment. A blanket will be placed over the subject's chest and only lowered about 10 cm below the clavicle. With the subject lying quietly the TDC sites to be measured will be marked with a surgical pen. These sites are located bilaterally on the anterior chest, the anterior forearm, and just below the medial malleolus. The arm site is 10 cm distal to the antecubital fossa and the ankle site about 2.5 cm below the center of the medial malleolus (inner ankle bone). The chest sites are shown in figure 1. Site "L" is located by palpating the sternal angle to obtain the location of the 2nd rib.

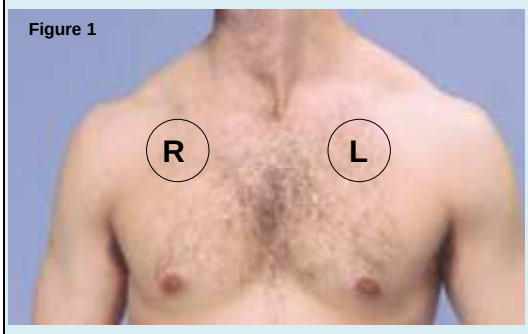

Figure 1

The TDC measurement site is to be within the first intercostal space between 1st and 2nd ribs at the midline of the clavicle. A corresponding site "R" will be measured also in the same manner as site "L". To prepare for the measurement of whole body water and fat percentages using a bioimpedance method (Bodystat®1500), two electrodes will be placed on the left foot and two electrodes on the left hand. The details of this measurement device are in Section B. Once the body fat and water percentages are recorded, the electrodes will be removed from the subjects hand and foot. A blood pressure cuff will then be placed on the subject's left arm and connected to an automatic blood pressure device (Section C). Once the subject's blood pressure and pulse are recorded, the blood pressure cuff will be removed from the patient's left arm. Following these initial procedures which take about 10 minutes total, TDC measurements will start and will take about 12 minutes (Section D). Once the TDC data has been recorded, the subject will be asked to put on their shoes, socks, and shirt. Once this is done, the subject will

be given the opportunity to ask any questions, comments, or concerns. The time required for the entire experimental procedure is about 30 minutes.

B. Methods for Measurement of Bioimpedance (Bodystat®1500)

The device is a hand-held, battery operated, noninvasive bioimpedance analyzer. It measures

the electrical impedance value of the body providing a quick and effective analysis of whole body composition. It has two main cable leads and each lead has two crocodile/alligator clips, red and black. These clips are attached to the exposed tabs on the electrodes. The subject's gender, age, height and weight are entered using a keypad. Whole body impedance is measured by passing a very low level battery generated signal through the body and measuring the impedance at a fixed frequency of 50 kHz. Once the test has been performed a complete body composition analysis is displayed on the LCD screen within three seconds. Relevant parameters determined and displayed include body fat, lean body mass and total body water (15). This device has been utilized and validated in several research studies (15,16,17) and is FDA cleared for use in the United States (See enclosure)

C. Methods for Measurement of Blood Pressure [Omron M7 (HEM-780-E)]

The Welch Allyn Flexiport Reusable Blood Pressure cuff will be used to quantify blood pressure

for all subjects. It is composed of a latex free material that reduces chances of an allergic reaction and is an operator friendly device. Other benefits of this cuff include: rotatable port which decreases the stress to the apparatus thus improving the comfort level of the subject, a folded edge which decreases the chance of cuts/scrapes to the subject, and meets the latest clinical guidelines for proper fit by the AAMI and AHA.

D. Methods for Measurement of Tissue Dielectric Constant (TDC)

The method is based on the principle that the tissue dielectric constant (TDC) is directly related

to the amount of free and bound water contained in the measuring volume correlated with the amount of tissue water at the particular site (19-21). The machine used to assess the TDC is a battery operated machine called the MoistureMeter-D pictured above (Delfin Technologies Ltd. P.O. Box 1199 Kuopio Finland). TDC is assessed by utilizing gold plated-brass open-ended coaxial probes attached the MoistureMeter-D measuring unit. The probe measures TDC at a frequency of 300 MHz, which is displayed on the face of the unit. Each probe measures to a different depth. In this study we will use probes that have effective penetration depths of 2.5 mm and 5.0 mm. For reference, pure water has a TDC value of 78.5. As noted previously the sites of interest are the anterior forearm, the medial malleolus area and the subclavicular area.

TDC measurements will be made at each marked site in the order as follows:

1) Site L
2) Site R
3) Right forearm
4) Left forearm

5) Left medial malleolus
6) Right medial malleolus

The 2.5 mm will be used first at all measurement sites in the order of 1 through 6. Steps 1-6 will be repeated twice more to yield triplicate measurements at each site. Thereafter, the 5.0 mm probe will be used. For this probe only steps 1 through 4 will be done in triplicate. This device has been used and validated in several research studies (22-26).

E. Cited References

1. Mayrovitz HN. Assessing local tissue edema in postmastectomy lymphedema. Lymphology. 2007: 40(2): 87-94.
2. Mayrovitz HN, Brown-Cross D, Washington Z. Skin tissue water and laser Doppler blood flow during a menstrual cycle. Clin Physiol Funct Imaging. 2007: 27(1): 54-9.
3. Mayrovitz HN, Davey S, Shapiro E. Local tissue water changes assessed by tissue dielectric constant: single measurements versus averaging of multiple measurements. Lymphology. 2008: 41(4): 186-8.
4. Mayrovitz HN, Davey S, Shapiro E. Localized tissue water changes accompanying one manual lymphatic drainage (MLD) therapy session assessed by changes in tissue dielectric constant inpatients with lower extremity lymphedema. Lymphology. 2008: 41(2): 87-92.
5. Mayrovitz HN, Davey S, Shapiro E. Local tissue water assessed by tissue dielectric constant: anatomical site and depth dependence in women prior to breast cancer treatment-related surgery. Clin Physiol Funct Imaging. 2008: 28(5): 337-42.
6. Mayrovitz HN, Davey S, Shapiro E. Suitability of single tissue dielectric constant measurements to assess local tissue water in normal and lymphedematous skin. Clin Physiol Funct Imaging. 2009: 29(2):123-7.
7. Miettinen M, Monkkonen J, Lahtinen MR, Nuutinen J, Lahtinen T. Measurement of oedema in irritant-exposed skin by a dielectric technique. Skin Res Technol. 2006: 12(4): 235-40.
8. Mayrovitz HN, Macdonald J, Davey S, Olson K, Washington E. (2007) Measurement decisions for clinical assessment of limb volume changes in patients with bilateral and unilateral limb edema. Physical Therapy 2007 (October) 87: (10) 1362-1368.
9. Mayrovitz HN, Sims N, Pfister S, Litwin B (2005). Foot volume estimates based on geometric algorithm in comparison to water displacement. Lymphology 2005;38(1):20-27
10. Mayrovitz HN. (2007). Interface pressures produced by two different types of lymphedema therapy devices. Physical Therapy (October) 87:(10) 379-1388.
11. Robinson MK (1999) Population differences in skin structure and physiology and the susceptibility to irritant and allergic contact dermatitis: implications for skin safety testing and risk assessment. Contact Dermatitis 41:65–79
12. Stern RS, Momtaz K (1984) Skin typing for assessment of skin cancer risk and acute response to UV-B and oral methoxsalen photochemotherapy. Arch Dermatol 120: 869-73.
13. Berardesca E, Pirot F, Singh M, Maibach H. Differences in stratum corneum pH gradient when comparing white Caucasian and black African-American skin. Br J Dermatol. 1998: 139: 855-857.
14. Tadokoro T, Yamaguchi Y, et al. Mechanisms of Skin Tanning in Different Racial/Ethnic Groups in Response to Ultraviolet Radiation. Melanocyte. 2005: 1326-32.
15. Ghosh S, et al. Body composition at the bedside. Eur J Gastroenterol Hepatol. 1997 Aug; 9(8): 783-8.
16. Simpson, J, et al. Body water compartment measurements: A comparison of bioelectrical impedance analysis within tritium and sodium bromide dilution techniques. Clin Nutr. 2001 Aug; 20(4): 339-43.
17. Suchanek P, et al. Actigenetic of ACE gene polymorphism in Czech obese sedentary females. Physiol Res. 2009; 58 suppl 1: S47-52.
18. Coleman A, Steel S, Freeman P, de Greeff A, Shennan A. Validation of the Omron M7 (HEM-780-E) oscillometric blood pressure monitoring device according to the British Hypertension Society. Blood Pressure Monitoring 2008, 13:49-54
19. Aimoto A, Matsumoto T. Noninvasive method for measuring the electrical properties of deep tissues using an open-ended coaxial probe. Med Eng Phys. 1996: 18(8): 641-6.
20. Alanen E, Lahtinen T, Nuutinen J. Measurement of dielectric properties of subcutaneous fat with open-ended coaxial sensors. Phys Med Biol. 1998: 43(3): 475-85.
21. Alanen E, Lahtinen T, Nuutinen J. Penetration of electromagnetic fields of an open-ended coaxial probe between 1 MHz and 1 GHz in dielectric skin measurements. Phys Med Biol. 1999: 44(7): N169-76.
22. Nuutinen J, Ikaheimo R, Lahtinen T. Validation of a new dielectric device to assess changes of tissue water in skin and subcutaneous fat. Physiol Meas. 2004: 25(2): 447-54.
23. Nuutinen J, Lahtinen T, Turunen M, Alanen E, Tenhunen M, Usenius T, et al. A dielectric method for measuring early and late reactions in irradiated human skin. Radiother Oncol. 1998: 47(3): 249-54.
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26. Stuchly MA, Athey TW, Stuchly SS, Samaras GM, Taylor G. Dielectric properties of animal tissues in vivo at frequencies 10 MHz--1 GHz. Bioelectromagnetics. 1981: 2(2): 93-103.

Part 4 – Sources of Data Information

Are you using questionnaires, tests, instruments, or forms? Yes [X] No [ ]

If "Yes", list them below and include a copy of each as appendices.

Questionnaire (Appendix 1)
Devices used with description (Appendix 2)

Do you plan to use any data from records or archives? Yes [ ] No [X]

If "Yes", please describe (such as data originally created for non research purposes or data created as a result of a previous study).

Do you plan to use any de-identified data? Yes [X] No [ ]

If "Yes", please describe the data and how it will be de-identified.

Data collections tools will only have a subject de-identification number instead of name to protect health-related information of the study subjects and be in compliance with HIPAA regulation. A list with the subject's name and de-identification number and the data files will be kept in different locked cabinets in room 1313 of the Terry building. Dr. Mayrovitz and the CIs will have access to these locked cabinets. Dr. Mayrovitz will hold the key to these cabinets. The patient will not be contacted if any pertinent health information is discovered.

3. Additional Study Information

3.A. Clinical Testing

Food and Drug Administration
Investigational Drugs and Devices

Does the study involve the use of an investigational drug? Yes [ ] No [X]

If "Yes", has an Investigational New Drug application been submitted for the drug? Yes [ ] No [ ]

Does the study involve the use of an investigational device? Yes [ ] No [X]

If "Yes", has an Investigational Device Exemption (IDE) been, or will be, secured prior to the start of the study? Yes [ ] No [ ]

Does the study use any device (either as a part of the experiment or to collect data) that has not received FDA approved for clinical/medical use or is being used in a manner not consistent with its cleared/marketing status? Yes [X] No [ ]

If "Yes", please describe the device and how its use differs from its approved status by the FDA.

The Moisture Meters D has not been submitted by the manufacturer for FDA approval. They are being used in this study strictly as research measurement tools.

Clinical Procedures		
Does the study involve the use of any procedure that is not used in routine clinical practice?	Yes: X	No:

If "Yes", please list the procedures.

The method is based on the principle that the tissue dielectric constant (TDC) is directly related to the amount of free and bound water contained in the measuring volume correlated with the amount of tissue water at the particular site (19-21). The machine used to assess the TDC is a battery operated machine called the MoistureMeter-D (Delfin Technologies Ltd. P.O. Box 1199 Kuopio Finland). TDC is assessed by utilizing gold plated-brass open-ended coaxial probes attached the MoistureMeter-D measuring unit. The probe measures TDC at a frequency of 300 MHz, which is displayed on the face of the unit. Each probe penetrates to different depths. We will be utilizing probes that have effective penetration depths of 2.5 mm and 5.0 mm. The TDC values range from 1-80. For example, water has a value of 78.5.

3.B. Sensitive Information

Are you asking questions about sensitive issues, such as illegal activity, sexual history, or anything else that, if made public, could jeopardize a person's reputation, employability, safety, or quality of life?	Yes:	No: X

If "Yes", please describe the information.

N/A

Does the study involve the collection of data from voice, video, digital, or image recordings made for research purposes?	Yes:	No: X

If "Yes", please describe the procedures associated with these recordings.

N/A

3.C. Non-English Speaking Participants

Will the study involve non-English speaking participants?	Yes:	No: X
Will the study require translation of consent forms?	Yes:	No: X

If you answered "Yes," please specify the language(s) that the consent forms will be translated in to:

N/A

If you are including non-English speaking participants, when you complete section III.H., please discuss how you will ensure that the participants understand the study, including the use of a qualified translator to provide oral consent information.

3.D. Subject Compensation

Will your subjects receive any payments, incentives, or gifts?

Yes	No
X	

If "Yes," please indicate the types of compensation. Otherwise move on to section E.

Monetary Payment	Gift	Extra credit (Students) or Workplace Incentive (Employees)
	X	

Other incentive

Please describe:

All subjects will receive a complimentary movie ticket.

Describe the payment(s)/gift(s)/incentive(s), and if it is a gift, estimate its monetary value. Indicate whether all participants are given the payment/gift/incentive, or if only some are eligible. (Note: the value of the payment/gift/incentive should not be so significant that it might compromise the subject's good judgment.)

The ticket is for Regal Cinema only. It is worth $7.50 and does not have an expiration date. If lost or stolen, a replacement ticket will not be awarded.

Describe when the subject will receive the payment/gift/incentive, and whether the amount differs depending upon whether different portions of the study are completed or is limited if the subject discontinues participation during the study.

All participants who begin the study will receive a movie ticket regardless if they remain a subject for the entire study.

3.E. Inclusion / Exclusion Criteria for Subjects

Describe the inclusion and exclusion criteria for the proposed subjects. Please list the criteria in bullet or outline format rather than narrative. If the study limits participation based on gender, age or race, please justify the exclusion criteria. (Subject protection and appropriate study design may require specific inclusion or exclusion criteria, but the IRB does not permit subject selection that is not equitable or prevents a subpopulation from benefiting from the scientific discoveries of the study.)

Inclusion Criteria

Subject must attest to overall good health with no cardiac or vascular complications
Males and females between the ages of 18-48
Must be either in Asian-Indian, Hispanic, Blacks, White or Asian racial group

Exclusion Criteria

Any implanted wires, cardiac pacemaker or any other electronic medical devices
Open wounds anywhere that a local measurement is to be made (forearm, ankle or chest)
Alcohol consumption 24 hrs prior to assessment
Use of diuretics
Pregnancy

3.F. Subject Recruitment

How will you recruit subjects (approach/invite/or ask people to be in your study)?

The CIs will approach students and invite them to participate. The invitations will be verbal and there will not be any fliers. The participants will not be advised or taught by the PI.

Recruitment Advertisements, Fliers, and Letters

Are you using any letters, fliers, or advertisements?	Yes	No
		X

If you answered yes, please list the type(s) below and attach a copy of the proposed materials as an appendix (do not copy and paste the flyer into this form).
(Note: Materials should list "Nova Southeastern University".)

N/A

3.G. Potential for Coercion in Subject Recruitment

	Yes	No
Are any of the subjects a student or advisee of the PI or a Co-I?		X
Does the PI or a Co-I serve in any capacity (e.g., administrative, therapeutic) that might affect a subject's willingness to participate?		X

If "Yes" to either of the above, then describe the relationship of the subjects and investigator.

N/A

If you answered yes, please read the NSU policy about use of students in research.
http://www.nova.edu/irb/manual/forms/research_students_subjects.pdf

	Yes	No
Are any of the subjects employees of, or report to, the PI or a Co-I?		X
Are any of the subjects a patient of the PI or a Co-I?		X
Are any of the subjects a patient within a PI or a Co-I's clinical practice?		X
Are any of the subjects informed about the study by their doctor / clinician?		X

If you answered "yes" to any of the questions in this section (3.G.), please describe how you will ensure that the subjects will feel free to decline participation without fear of reprisal. If the subjects are patients, how will you prevent "therapeutic misconception" (the mistaken belief that when a care provider provides information about a study, it means that the provider thinks that study participation will benefit the patient).

N/A

If you are providing any incentive to the student/employee subjects, discuss whether there is a mechanism for students / employees to receive the incentive by doing something other than participating in the research project (see http://www.nova.edu/irb/manual/forms/research_students_subjects.pdf).

N/A

3.H. Informed Consent

Part 1 – Consent Process

Informed consent is a process that begins with advertising or telling potential subjects about your study, continues as the investigator or staff provides details to potential subjects via dialog, and is formalized by the signing of the consent.

Note: Minors must have consent of their parents or guardians before you can approach the minor about participating in the study.
Note: Allow as much time as possible and feasible for the subject to think about whether to enroll in the study. Generally, the greater the study risks, the longer the decision period.

Please overview the steps in the consent process in your research study. If there is more than one group of subjects, separately describe the process for each group.

In the privacy of room 1305A of the Terry building, one of the co-investigators will describe the study to potential participants, answer any questions they may have and oversee the signing of the consent form. The participants will immediately be provided with a copy of the signed form. All potential participants will be given the opportunity to meet with the principal investigator in his office prior to, or after consenting if they should so desire.

Part 2 – Consent Process and Document Waiver/Alteration Information

In most cases, subjects need to participate in a meaningful consent process and receive a consent/assent form that documents agreement to participate in research. However, in a few cases the subject's confidentiality is protected by waiving/altering consent procedures or the requirement for signed consent forms. Please read the IRB's policy on informed consent for explanations, including what the IRB must demonstrate to permit waiver or alteration (http://www.nova.edu/irb/manual/forms/informed_consent.pdf). Please note, however, that while your study may qualify for waiver or alteration, that determination is at the discretion of the IRB.

One case where a signed informed consent form is NOT used is when a researcher is only reviewing existing/archival data that were collected for non-research purposes. If the data are obtained from the records by someone with authorization, and the data are de-identified, then it may be appropriate not to ask subjects (those whose data you are collecting) to provide consent, because the research involves no more than minimal risk, the waiver or alteration will not adversely affect the rights or welfare of subjects, the research could not practicably be carried out without the waiver or alteration, and, when appropriate, the subject will be provided pertinent information about participation. (NOTE: If your study has other procedures that require interaction with subjects or prospective collection of data, it is unlikely that waiver or alteration of consent procedures or the signing of consent forms would be appropriate.) If this describes your study, then you may request a waiver of the requirement for informed consent and the documentation of signed consent.

If you think this applies in your study, please describe your rationale.

N/A

Another situation involving waiver or alteration of the requirement to obtain a signed consent form is when the research only entails conducting anonymous surveys that are not intrusive. If there is no way that the subjects' responses could be linked to them, then waiving the requirement for a signed consent form would minimize a risk to their confidentiality and privacy because the only record linking the subject and the research would be the consent form. If the principal risk would be potential harm resulting from a breach of confidentiality and the research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research context, then the elements of informed consent are put into the survey itself. The person indicates his/her voluntary participation by completing the survey after being advised about the study and voluntary nature of his/her participation.

If you think this applies in your study, please describe your rationale.

N/A

There may be other cases where you would wish to ask for a waiver or alteration of informed consent or signed consent documentation.

If you are seeking a waiver or alteration, please describe your rationale.

N/A

Part 3 – Consent and Assent Document Information

Typically, you are asked to use the NSU format consent and assent forms. However, if this is cooperative research, or sponsored research that requires the use of a different template or model, you may use their format.

I will use NSU format consent/assent forms	X
I will be using another institution's format for consent/assent forms (NOTE: Please review the other institution's consent forms and the NSU requirements to be sure that all of the NSU requirements are present. You may also want to discuss the consent forms with your college/center representative)	
As noted above, I am requesting a waiver/alteration of consent and/or signed consent form requirements	

If you have different procedures for different groups of subjects, you will need a separate consent and/or assent form for each group. If the reading level of different groups of subjects differs, this may also require you to have different consent and/or assent forms (e.g. young children vs adolescents). If your subjects are children, you will also need parental consent.

What is the total number of consent/assent form types that you plan to use?

1

If using more than one consent form, create a list below that describes the different forms that you will be using (e.g. 1. Teacher consent form, 2. Parent consent form, 3. Assent form for children age 7-12, 4. Assent form for adolescents).

N/A

Include copies of the consent / assent forms. When you attach the consent forms, put them in this

order. Please note that the IRB prefers that the consent document be written using the simplest language possible, and strongly recommends the question and answer format (see Document Model #1 for Adult/General Consent Form [Readability Score: Grade 6]).

3.I. Protected Health Information Use

	Yes	No
Are you obtaining any data from the subject's medical record?		X
Are you asking the subject about his or her health information, and doing so in a clinic or entity that would normally be subject to HIPAA regulations on protected health information?		X

If you answered "Yes" to either question, continue. Otherwise go on to section 3.J.

Please review the NSU HIPAA research policies available at (http://www.nova.edu/irb/manual/policies.html for more information.

Please note that effective 12/10/2009 the NSU IRB no longer reviews separate HIPAA authorizations for research. It is the principal investigator's responsibility to use the correct HIPAA authorization as outlined in the aforementioned policy. In instances where the HIPAA authorization must be a part of the informed consent form for research, the NSU IRB will review the compound consent.

Specify the exact data to be gathered (e.g., weight, blood pressure, IQ score, diagnosis, depression rating, number of treatments, etc.).

Which procedure are you proposing to use? (Check)

I will obtain the subject's authorization to obtain the protected health information via the NSU Authorization for Use and Disclosure of Protected Health Information in Research (research activities will be occurring at an NSU clinic).	
I will obtain the subject's authorization to obtain the protected health information via the authorization for use and disclosure of protected health information in research provided by the non-NSU covered entity.	
The protected health information data are a fully de-identified data set (data obtained without recording any patient information, with the data accessed by an employee of the institution).	
The data are part of a limited data set agreement as defined by the Office of Human Research Protections. (Attach a copy of the agreement.)	

If part of a limited data set agreement, what is the justification that confidentiality is protected?

I have a waiver provided by a duly constituted privacy board. (Attach a copy of the waiver.)

HIPAA Research Authorization

If the research is to be conducted at an NSU clinic, have you created a HIPAA authorization form as outlined in the HIPAA Research Policy No. 1 (http://www.nova.edu/irb/manual/policies.html) and in keeping with the Instructions for Preparing the Authorization For Use and Disclosure of Protected Health Information in Research Form and the model form provided (http://www.nova.edu/irb/manual/forms.html)?

Yes	No

Please note, do NOT submit a copy of the HIPAA authorization form if you are following the model

noted in the aforementioned policy.

If the research is to be conducted at a non-NSU covered entity, have you reviewed the HIPAA Research Policy No. 6: Guidance on Research at Outside Entities (http://www.nova.edu/irb/manual/policies.html)?

Yes	No
☐	☐

Researchers are advised to discuss the proposed research with the applicable HIPAA privacy officer at the non-NSU covered entity.

Does the researcher sponsor or cooperating agency require the incorporation of the HIPAA authorization within the consent document (Compound Consent)?

Yes	No
☐	☐

If yes, please briefly indicate who requires that this be in the informed consent document.

N/A

Please note, consent forms that include the HIPAA authorization may need approval from the university Office of Corporate Compliance.

3.J. Student/Academic Information Use

Are you obtaining any data from the subject's academic records?

Yes	No
☐	X

If you answered "Yes", continue. Otherwise go on to section K.

Specify the exact data to be gathered (e.g., GPA, standardized test score, IQ score, medical/psychological information stored in academic files, attendance records, disciplinary records, etc.).

N/A

Specify how you will obtain the data.

N/A

Which procedure are you proposing to use? (Check all that apply)

I will obtain the subject's consent to obtain the academic information. ☐

The academic information will be a part of a fully de-identified data set (data obtained without recording any subject information, and provided to you in keeping with the institution's policies and the Federal Educational Rights and Privacy Act [FERPA]). ☐

3.K. Risks, Discomforts, & Inconveniences

In this section, discuss all potential risks (physical, economic/financial, legal, psychological, social, etc.), discomforts, or inconveniences to the subjects.

- All studies using identifiable subject information must address the issue of possible loss of subject confidentiality
- Some possible risks include physical, psychological or emotional harm, breach of confidentiality, and invasion of privacy.

- Discomfort includes anticipated risk for mild physical or emotional pain.
- Study inconveniences include loss of time or pay.

Each risk, discomfort and inconvenience should be addressed individually in the following format (use the tables provided and copy if the study presents more than 3).

- List each item individually
- Discuss likelihood: How likely is it that this risk/discomfort or inconvenience will occur? This is usually classified as minimal, moderate, or high.
- Discuss magnitude/duration: How dire is the risk/inconvenience/discomfort, and if it occurs, how long do you expect that the subject will be affected?
- Discuss risk minimization: Describe the procedures undertaken to minimize the risk that this specific risk/discomfort/inconvenience will occur.

Risk/Discomfort	Tingling of arm or hand or related discomfort when the blood pressure cuff is inflated and/or released
Likelihood	Moderate
Magnitude/Duration	Low risk/Transient – seconds
Risk Minimization	Subject will be encouraged to verbalize discomfort. If discomfort is felt the CI will fully release the blood pressure cuff.

Risk/Discomfort	Touching or slightly pressing of the skin at any of the measured sites may cause tickling or pressure or other sensation of susceptible subjects
Likelihood	Low
Magnitude/Duration	Low risk/Transient – seconds
Risk Minimization	If present and not tolerable by subject will abandon study on this subject

Risk/Discomfort	Tingling or pain in foot or hand or related discomfort when the adhesive electrodes are removed from skin
Likelihood	Low
Magnitude/Duration	Low risk/Transient – seconds
Risk Minimization	If present and not tolerable by subject will abandon study on this subject

One way in which confidentiality is partially protected is to destroy study documents containing identifiable information when they are no longer needed. The IRB requires that study materials be kept for a minimum of three years from the end of the study to permit study auditing; you may elect to keep them for a longer period of time and study sponsors may have their own data retention requirements. Please indicate when and how you plan to destroy data that contains identifiable subject information, such as consent forms, lists that link subject identity to data coding, or raw data containing subject names.

To avoid the risk of possible loss for protected health information and confidentiality, all records and signed informed consents will be kept confidential and protected for five years. Only the principal and co-investigators will have access to this information. With respect to data security, any data collected and used for analysis will be identified only with a number. A list containing the participants' names and corresponding de-identification numbers will be stored in a locked file cabinet in room 1313. The data files and the list of subject names will be kept in separate cabinets. The keys to the cabinets will be held by Dr. Mayrovitz and the CIs will have access to them. The risk of loss of confidentiality is minimal.

3.L. Benefits to Subjects

In this section, discuss all direct benefits of the study to participants. This does not include "helping research" or other generalities, nor does it include compensation for participation. Some examples of benefits include receiving free treatment, receiving a list of reputable local services, or obtaining tutoring. The value of any such benefits should be listed as well. If there are no direct benefits to the participants, this should be indicated.

Are there any direct benefits to the research participants?

There are no direct benefits to study participants	This study provides benefit to, or is likely to benefit, the participants
X	

List/describe each benefit

N/A

3.M. Data Analysis Plan

Please describe preliminarily proposed data analysis procedures.

The data collected will be analyzed to predict whether there are differences in skin tissue water levels amongst different racial groups and to predict correlations between skin tissue water and total body water percentages. Further analysis will predict which part of the body has a higher basal tissue body water index within certain racial groups. The PI will compare and characterize whether there is a difference in TDC values among different racial groups and where these differences are. The general analytic method to be used will consider the effects of the two maneuvers on TDC independently. The initial questions to be answered are whether TDC values fluctuate among racial groups and if so, what are the quantifiable variations. The subsequent question to be answered is what quantifiable relationship exists between TDC values and total body water percentage. To determine this, the average of the TDC values obtained during the TDC measurements will be compared among the different races along with gender. Statistical testing of possible differences will be tested using paired-t statistical tests.

3.N. Scientific Benefit

Briefly discuss how generalization of the information obtained from this study will be scientifically useful, or useful to your research site.

The data set obtained will represent an important reference data base to enhance understanding of several skin related physiologic issues. Further, since the TDC method is widely used in research and new clinical arenas the present study will allow for a better understanding of the differences in tissue body water amongst different racial groups that impact the measured TDC value. Finally, TDC values and their change are related to skin tissue water concentration. Therefore, the present study should also provide basic information on the effect of the above parameters in normal skin tissue water of different racial groups. These findings could contribute to the enhancement of treatment in patients of different races, who suffer from lymphedema and/or any disease where fluid retention of the skin is involved.

3.O. Risk/Benefit Ratio

To be approved, a study needs to have greater benefits than risks. Why do you believe this study has a positive benefits-to-risks ratio?

The risks are similar to those that would be experienced in daily life whereas the scientific benefit is likely to be significant. By gaining the knowledge and understanding the distribution and factors involved in the overall tissue body water content, we can add new quantifiable information illustrating variations in skin among Asian Indian, Black, Hispanic, White, and Asian.

3.P. Safety Monitoring Plans

All researchers are required to report adverse events and unanticipated problems in keeping with the NSU IRB policy (http://www.nova.edu/irb/manual/forms/adverse_events.pdf).

Studies that entail significant risk to subjects, such as randomized controlled drug trials, may warrant safety monitoring by an outside safety board. Does your study utilize a Data Safety Monitoring plan?

Yes	No
	X

If "Yes," please describe the safety monitoring plans. Please specify if the study will be monitored by the investigators, sponsors (if applicable), or a Data Safety Monitoring Board (DSMB). Sponsored studies may reference an attached Investigator Brochure.

N/A

3.Q. Other Information

If there is other information about this study that is required in order for those reviewing the study to fully understand the study, its risks and benefits, please describe below.

N/A

3.R. Principal Investigator Assurance and Obligations

I certify that all information provided in this submission (including any supporting documents) is a complete and accurate description of the proposed study. I agree to the following:

This study will be conducted in the manner described in this submission and will not be implemented (including subject recruitment or consenting) until all applicable IRBs have granted permission to conduct the research. No changes to this study will be implemented until an amendment form has been submitted and approved by the IRB.

PI Initials	HNM

If the IRB approves this study via expedited or full procedure, I will submit for continuing review as stipulated in the approval letter. If the study or data analysis will exceed the approval period, I will submit a Submission Form for Continuing Review of IRB Approved Studies in a timely manner (well in advance of the renewal date). I understand that study activities may not continue past an approval period.

PI Initials	HNM

I will provide a copy of the signed consent form to the subject or patient, if applicable.

PI Initials	HNM

I will retain all signed informed consent documents and study-related records for a minimum of three (3) years (or longer as stipulated by funding agencies) from the date the study is concluded.

PI Initials	HNM

I will report in writing any serious adverse events to the IRB within 24 hours and all other adverse events and unanticipated problems within 5 working days.

PI Initials	HNM

I will provide participants with any significant new information obtained during the course of the study and submit reports of new information to the IRB as a Study Amendment.

PI Initials	HNM

If my study has been approved at the Expedited or Full Review levels, I will report to the IRB when this study has closed (no further data collection or analysis). This report will be provided no later than 30 days after the end of the study via the IRB Closing Report Form.

PI Initials	HNM

Principal Investigator's Signature: _____ Date: _____

3.S. Co-Investigator Assurance and Obligations (for Student PIs)

If this study is for the completion of a degree requirement, the thesis adviser or dissertation chair must sign the attestation below.

- All departmental approvals by the student's committee (if applicable) and chair or thesis adviser have been completed.
- I accept that the University and IRB consider the faculty advisor's responsibility to be equal to that of the student in regard to
  - The quality of the research design AND the accuracy of the protocol
  - The appropriateness of the recruitment methods, the design of the process for informing the subjects about the nature of the study, and the process of obtaining informed consent
  - The readability, accuracy, and format of the informed consent/assent document(s) and the explanation of all informed consent procedures.

My signature below attests that I have read this submission in its entirety and believe that it is accurate, complete, appropriate, and adheres to the principles of the Belmont report and that all departmental approvals by the student's committee have been completed.

Chair/Adviser's Signature: _____ Date: _____