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:

Effect of Changes in Skin Vascular Volume and Blood Flow on Skin 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 goal of this investigation is to determine the extent to which skin vascular volume and skin blood flow affects the tissue dielectric constant (TDC) of the skin. 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 in conditions such as lymphedema and patients with breast cancer (1-7). Because skin vascular volume and blood flow vary among patients and also vary in the same patient at different times, it is important to determine if and to what extent these factors impact the TDC measurement. Information bearing on this issue will be determined in this study by increasing and decreasing skin vascular volume and by modifying blood flow and determining

the effect of such changes on the measured values TDC. Blood volume of the forearm will be increased by inflating a standard blood pressure cuff around the bicep to a pressure of 50 mmHg for four minutes. Blood volume will be decreased by supporting the subject's arm above heart level for five minutes. All procedures and measurements will be done with subject supine. Each maneuver will also modify skin blood flow which will be measured with the non-invasive laser Doppler method. The acclimation, setup and measurement sequence will require one subject visit lasting about 60 minutes. A total of 40 subjects will be recruited for participation in this research study.

1.D. Principal Investigator (PI) Information			
Name	Harvey N. Mayrovitz	Relationship to NSU	
Mailing Address (for Students)			
Interoffice Mail Code (for Faculty/Staff)		Student	
Daytime Phone	954-262-1313	Faculty	X
Alternate Phone		Staff	
NSU Email Address	mayrovit@nova.edu	NSU Center/College/Dept	
Alternate Email Address		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 Professor of Physiology in the College of Medical Sciences. Over 15 years research experience as exemplified by the following sampling of peer reviewed research publications.

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

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

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

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

Mayrovitz HN, Groseclose EE (2005). Inspiration-induced vasoconstrictive responses in dominant vs. nondominant hands. Clin Physiol Funct 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 2005;38:81-86

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 blood flow during a menstural 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). Localized Tissue Water Changes Accompanying One Manual Lymphatic Drainage (MLD)Therapy Session Assessed by Changes in Tissue Dielectric Constant in Patients with Lower Extremity Lymphedema Lymphology 2008;41:87-92

Mayrovitz HN, Davey S, Shapiro E (2008). Local tissue water changes assessed by tissue dielectric constant: Single measurements versus 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 and 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 Planimetry 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.

Lymphatic Research and Biology 2009;7(2) 101-109
Mayrovitz HN (2009). Assessing Lymphedema by Tissue Indentation Force and Local Tissue Water. Lymphology 2009;42:88-98
Mayrovitz HN (2009). Local Tissue Water Assessed by Measuring Forearm Skin Dielectric Constant: Dependence on Measurement depth, Age and Body Mass Index. Skin Research and Technology (in press)
Mayrovitz HN, Weingrad D, Davey S. (2009). Local Tissue Water in At-Risk and Contralateral Forearms of Women with and without Breast Cancer Treatment-Related Lymphedema. Lymphedema Research and Biology (in press)

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

	Co-Investigator 1	Co-Investigator 2	Co-Investigator 3
Name	Matthew Uhde	Mark Salmon	Xiaoran Guo
Mailing Address	1118 NE 1st Ave. Fort Lauderdale, Fl 33304	711 N Pine Island Rd #210 Plantation, FL 33324	7060 Nova Drive, Apt. 204C, Davie, FL, 33317
Contact Phone Number	954-558-7995	207-899-9419	954-864-2477
Email Address	mu80@nova.edu	markuscreek24@gmail.com	xiaoron@gmail.com
Degree/Academic Information:	DO/2nd year medical student	DO/2nd year medical student	DO/2nd year medical student
CITI Completion Date*	May 2010	July 2010	May 2010

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

Matthew Uhde, MS-licensure as a physician assistant since 2002 practicing in emergency medicine.
Resarch experience:
Literature review for an analysis of re-vaccinating US population to small pox, Barry University, Miami Shores, Fl

Mark Salmon, BS
Publication
Ganter GK, Walton KL, Merriman JO, Salmon MV, Brooks KM, Maddula S, Kravitz EA. (2007) Increased Male-Male Courtship in Ecdysone Receptor Deficient Adult Flies. *Behavior Genetics* Vol. 37, Num. 3 (May 2007), p. 507-512
Research experience:
· Effects of steroid hormone system manipulation on oogenesis, aggression, and courtship in *Drosophila melanogaster*
· Effects of cocaine on prodynorphin knockout mice related to addiction, sensitization, and locomotor activity

Xiaroan Guo, BS
Research assistant:
University of Ottawa Heart Institute, Genetics Centre, 2008
University of Toronto, Centre for Research in Neurological Diseases, 2007

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				
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 X No ☐

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

HPD room 1305A of the Terry Building

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*						**40**		

Please briefly describe your potential subjects:

Subjects will be recruited from the HPD student body and faculty at Nova Southeastern University by word-of-mouth. No student who is being taught by Dr. Mayrovitz, the principal investigator, will be solicited for participation. There are to be no preferences with respect to gender or age except that all subjects will need to be at least 21 years of age.

*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	
Employees of the investigator or investigator's department	
Children (minors)	
Terminally ill	

Other (specify):

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

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.

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

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 primary purpose of this investigation is to determine the extent to which skin vascular volume and skin blood flow affects the tissue dielectric constant (TDC) of the skin.

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.

The main goal of this investigation is to determine the extent to which skin vascular volume and skin blood flow affects the tissue dielectric constant (TDC) of the skin. 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 in conditions such as lymphedema and patients with breast cancer (1-7). Because skin vascular volume and blood flow vary among patients and also vary in the same patient at different times, it is important to determine if and to what extent these factors impact the TDC measurement. Information bearing on this issue will be determined in this study by increasing and decreasing skin vascular volume and by modifying blood flow and determining the effect of such changes on the measured values TDC. Blood volume of the forearm will be increased by inflating a standard blood pressure cuff around the bicep to a pressure of 50 mmHg for four minutes. Blood volume will be decreased by supporting the subject's arm above heart level for five minutes. All procedures and measurements will be done with subject supine. Each maneuver will also modify skin blood flow which will be measured with the non-invasive laser Doppler method. The acclimation, setup and measurement sequence will require one subject visit lasting about 60 minutes. A total of 40 subjects will be recruited for participation in this research study. In order to provide a suitable characterization of the biophysical and tissue water related properties of the skin region under test, skin capacitance, transepidermal water loss and temperature at the skin target site will also be determined.

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.

METHODS

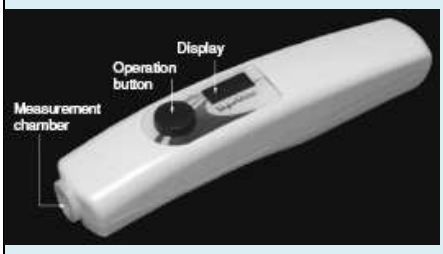
A. Protocol and Sequence Overview

Appendix 1 provides a flow diagram depicting the sequence of the major protocol events described below. Prior to any measurements one of the co-investigators will meet with prospective subjects, describe the study, answer any questions and administer the approved informed consent. All subjects will be asked to avoid applying any lotions or creams to their arms on the day of their research appointment. On the scheduled day and time, a subject will arrive at room 1305A of the Terry Building where measurements and procedures as described below and in sections B-G will be performed. Total time subjects will need to be present will be about 60 minutes (one visit only). All measurements are noninvasive and will be done with the subject supine on a padded examination table. Each skin parameter measurement will be done on the left anterior forearm at a target site located eight cm distal to the antecubital crease. This site will be marked with a surgical pen for reference. Prior to beginning the main protocol sequence, a series of baseline measurements will be taken. These include the measurement of the stratum corneum capacitance (SCC, section B), skin transepidermal water loss (TEWL, section C), skin temperature (section D) and the arm girth at the target site using a simple tape measure. In addition, the subject's blood pressure will be determined on the right arm using a standard cuff and sphygmomanometer (section E). Following these measurements the main protocols will be implemented. These consist of measurements aimed at determining the effect of changes in vascular volume and blood flow on the skin's tissue dielectric constant (TDC). This will be done using two types of maneuvers. One maneuver is the movement of the arm from a horizontal position to a near vertical position that causes a decrease in the target site vascular volume and a modification in skin blood flow. The other is mild compression of the bicep designed to alter venous vascular resistance and thereby increase vascular volume at the target site and also modify skin blood flow. These two maneuvers will done twice, first with measurements of TDC (section F) and then with measurements of skin blood flow using the laser Doppler method (section G). At the completion of these sequences the original baseline measurements will be repeated with the exception of the blood pressure measurement.

B. Method for Measurement of Stratum Corneum Capacitance as an Index of Hydration

The method is based on the principle that the measured electrical capacitance between the skin surface to a depth of about 100 um is an index of the relative water content of the stratum corneum (SC). The device to be used is the hand held battery operated MoistureMeter SC (8) manufactured by Delfin Technologies Ltd.(P.O. Box 1199 (Microkatu 1) 70211 Kuopio FINLAND) and pictured adjacent. A measurement is made by touching the skin surface with the end of the probe for about 10 seconds and the relative SC moisture is displayed on the device meter.

C. Method for Measurement of Trans-Epidermal Water Loss (TEWL)



The method is based on the principle that the flux of water (grams/m^2/min) leaving the skin can be quantified by collecting the effluent within a closed chamber and determining the change in relative humidity within the closed chamber. The device to be used for this purpose is the hand-held battery operated VapoMeter (9-14) manufactured by Delfin Technologies Ltd.(Op. Cit.) The measurement procedure requires the touching of the skin with the tip of the device for about ten seconds after which the TWEL value is automatically displayed.

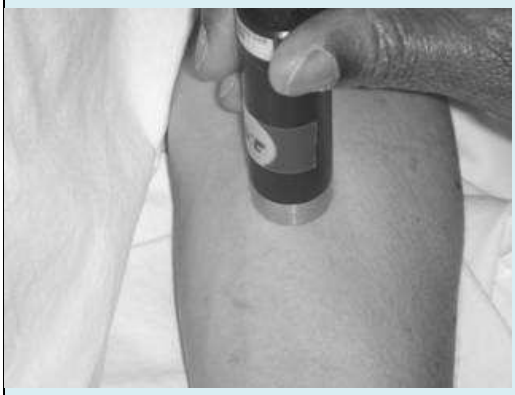
D. Method for Measurement of Skin Temperature

Skin temperature is to be measured with a non-contact infrared thermometer. Each measurement with this method takes about three seconds.

E. Blood Pressure Measurement

After the initial baseline measurements blood pressure will be measured on the right arm using a standard blood pressure cuff and sphygmomanometer.

F. Method for measurement of Tissue Dielectric Constant (TDC) for Local Tissue Water



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 (15-22). The device to be used is the battery operated Moisture Meter–D (Delfin Technologies Ltd. (Op. Cit.). The TDC of the target area is determined using a coaxial probe that makes contact with the skin for about ten seconds. The probe, which is connected to a control and display device, measures the TDC at a frequency of 300 MHz.

At this frequency the TDC is an index of both free and bound water. The penetration depth of the measurement depends of the probe size, with larger diameter probes penetrating deeper. The output parameter is the TDC value that has a range of 1 to 80. For reference, water has a value of about 78.5. For this study a probe with effective measurement depth of 1.5 will be used. These measurements will be taken at the measurement site described in section A. During the baseline measurements the subject's arm will have been in a horizontal position for at least two minutes. After this, the first maneuver set begins with TDC measurements taken every 20 seconds for three minutes. The arm is then passively raised by a co-investigator and supported vertically for five minutes with TDC measurements taken during the last three minutes of elevation. The arm is then passively lowered to the horizontal position. After two minutes of horizontal rest TDC measurements again taken every 20 seconds for three minutes. Then a blood pressure cuff around the bicep of the left arm will be inflated to 50 mmHg. After two minutes of inflation, TDC measurements will be taken every 20 seconds for three minutes. Once the last value is obtained, the blood pressure cuff will be released. If a patient's diastolic blood pressure is less than 60 mmHg, the pressure in the cuff will be adjusted downward accordingly so that it always at least 10 mmHg below arterial diastolic pressure. The total time for this measurement sequence including all intervals will be eighteen minutes.

G. Method of measurement of Skin Blood Flow

Skin blood flow (SBF) will be measured by a laser-Doppler flowmetry system (Moor Instruments, dual channel model). With this method the flux of red blood cells is detected by a small sensor taped to the skin. The sensor transmits a very low level laser light and also recovers the reflected signal that has a change in wavelength proportional to skin blood flow. The sensor is connected to a laser-Doppler monitoring and processing device via a fiber optic lead that converts the signal to blood perfusion units. This measurement method is in standard use clinically and for research purposes and its use for various purposes has been documented in over a thousand published papers. The principal investigator has used this technique for over fifteen years (2,23-34) and the device is FDA 510K registered. Measurements will be made at the same site as the previous TDC measurements and on the index finger dorsum using the dual channel capability. SBF data from these sites will be obtained following the completion of the previous TDC measurement series with its two-part arm maneuver sequence. After completion of the prior bicep compression sequence the laser Doppler sensors will be taped to the target forearm and finger sites. After the sensors are in place the arm will remain in a horizontal position for seven minutes while SBF is continuously recorded. After seven minutes in the horizontal position the arm will be passively raised to a vertical position for seven additional minutes while SBF continues to be recorded. Thereafter the arm will be passively returned to a horizontal position. After seven minutes in the horizontal position the blood pressure cuff will be inflated for five minutes. The total time required for these skin blood flow measurements is about 27 minutes.

Part 4 – Sources of Data Information		
Are you using questionnaires, tests, instruments, or forms? If "Yes", list them below and include a copy of each as appendices. Data Collection Form (shown in appendix 2)	Yes: X	No:
Do you plan to use any data from records or archives? If "Yes", please describe (such as data originally created for non research purposes or data created as a result of a previous study).	Yes:	No: X
Do you plan to use any de-identified data? If "Yes", please describe the data and how it will be de-identified.	Yes:	No: X

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? NA	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? NA	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 and SC and the VapoMeter have 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 Moisture Meters D and SC and the VapoMeter measurements.		

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.		
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.		

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:		
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)

Other incentive ☐

Please describe:

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.)

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.

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

Inclusion Criteria:

- Males and Females at least 21 years of age
- Willing to refrain from putting lotions or creams on their arms on their appointment day
- Ability and willingness to lie supine for up to 60 minutes

Exclusion Criteria

Exclusion Criteria:

Extensive hair on the anterior forearms
Individuals with contact dermatitis or prone to getting a rash when the skin is touched by that might be irritating
Open sores on the forearms
Any implanted wires or electronic medical devices
History of vascular problems with the upper extremities
History of blood clotting disorders
Pregnant women. There will not be any testing for pregnancy but female subjects who are of child bearing potential will be advised that if they believe they are pregnant they should not participate. Women known to be pregnant will be excluded, since we do not know whether pregnancy will impact the study

3.F. Subject Recruitment

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

Any of the co-investigators, who are M2 students in the Osteopathic Medicine program, will approach fellow classmates and friends and invite them to participate. They may also approach other HPD students in other programs but in no case will they approach any student being taught by Dr. Mayrovitz. The principal investigator will approach faculty and invite them to participate. The invitations will be verbal and there will not be any fliers. The following is a script the co-investigators and/or PI will use to recruit subjects: "We are conducting research on the effects of the skin's water content from changes in blood volume and blood flow in that area. There will be no audio or video recording of any kind, your name will not be attached to the information we collect, and all information is kept strictly confidential. All our procedures are non-invasive, and risk is minimal, meaning that the risks and discomfort to you will not be more than what you experience in everyday life. You are free at any time to stop the experiment for any reason. We will take 60 minutes of measurements, for which your arm will be raised for 15 minutes, and a pressure cuff will be around your upper arm for 5 minutes. If you feel discomfort at any time you may stop the experiment. There are no direct benefits or costs to you for participating. Would you like to be part of this study?"

Recruitment Advertisements, Fliers, and Letters

	Yes	No
Are you using any letters, fliers, or advertisements?		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".)

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.

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?	Yes	No

		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).

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).

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 or the principal investigator 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.

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.

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.

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).

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.).

Age, Height, Weight, Gender, Dominant Hand

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).	X
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.

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.).

Specify how you will obtain the data.

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	Will fully release cuff if subject indicates or complains of discomfort

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	
Likelihood	
Magnitude/Duration	
Risk Minimization	

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.

With respect to data security, any data (hard copy or electronic) collected and used for analysis will be identified only with a random number. This random number will be put on a copy of the consent form and stored in a locked file in room 1313. 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 [X]

This study provides benefit to, or is likely to benefit, the participants [ ]

List/describe each benefit

3.M. Data Analysis Plan

Please describe preliminarily proposed data analysis procedures.

The PI will compare and characterize whether there is a change in TDC values dependent upon vascular volume and blood flow. The general analytic method to be used will consider the effects of the two maneuvers on TDC independently. The central initial question to be answered is whether TDC values change with either the arm elevation maneuver or with bicep compression maneuver. To determine this, the average of the TDC values obtained during the pre-maneuver horizontal position will be compared with the average TDC values during the maneuver. Statistical testing of possible differences will be tested using paired-t statistical tests. Depending on the results of these initial analyses additional analyses that test for skin blood flow

maneuver-dependent changes and the impacts of such changes will be considered along with correlation analyses with respect to TDC association with baseline skin parameters and skin blood flow.

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 way in which vascular features and certain skin properties impact the measured TDC value. Finally because TDC values and their change are related to skin tissue water concentration the present study should also provide basic information on the effect of the above parameters on normal skin tissue water.

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.

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.

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.

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: _____