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UNIVERSITY OF TEXAS AT ARLINGTON
OFFICE OF RESEARCH

IRB FORM # 1
INITIAL SUBMISSION OF A RESEARCH PROTOCOL TO THE INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS

Faculty, staff, students, or employees who propose to engage in any research, demonstration, development, or other activity involving the use of human subjects must have review and approval of that activity by the Institutional Review Board, prior to initiation of that project. The Board is responsible for safeguarding the rights and welfare of subjects who participate in the activity.
If you require further assistance in completing this form or need additional information, please contact the Office of Research at extension 2105.

SECTION A: GENERAL INFORMATION

1. **Project Title:**

   The relationships among muscle strength, power, electromyography, mechanomyography, and fiber type of the vastus lateralis muscle during static and dynamic contractions.

2. **Principal Investigator:**
   - **Name**: Joel T. Cramer, Ph.D.
   - **Title:** Assistant Professor
   - **Department:** Kinesiology **Mail Box**: 19259
   - **Telephone**: 817-272-5784 **Email**: jcramer@uta.edu

3. **Co-Investigator:**
   - **Name**: Tanja Taivassalo, Ph.D.
   - **Title**: Assistant Professor, University of Texas Southwestern Medical Center, Dallas, TX
   - **Department:** Institute for Exercise and Environmental Medicine **Mail Box**: 7232 Greenville Avenue, Dallas, TX, 75231
   - **Telephone**: 214-345-6501 **Email**: tanjataivasslo@texashealth.org

4. **For a student submitting a protocol, please identify the faculty member responsible for conducting the research:**
   - **Name:**
   - **Title:**
   - **Department:** **Mail Box:**

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- **Telephone:** **Email:**

5. **Expected Start Date:** Upon IRB approval *(You are not authorized to start any research on human subjects until the IRB has approved the research protocol.)*

6. **Expected Completion Date:** Within 3 years of IRB approval. **(The IRB can only approve a research protocol for a maximum period of 3 years. If you require a longer period of approval for your research, you will have to submit a new protocol to the IRB on the 3-year anniversary date.)**

SECTION B: FUNDING If this research is not supported by funding, please skip to section C.

If you have or are seeking funding for your research, please specify the source.

7. **Source:** ☐ **FEDERAL (Specify Agency:)**

☐ **INDUSTRY SPONSORED (Specify Agency:)**

☐ **Local Departmental** ☐ **State** ☐ **Other:**

FUNDED GRANT / CONTRACT NUMBER:

☐ **Check here if grant is pending. Date of Grant Submission:**

8. **Do you plan to do the research if you do not receive funding?**

SECTION C: SUMMARY OF THE RESEARCH PROTOCOL

Please answer the following in simple, non-technical / non-exculpatory language.

9. **List primary research questions.**

Our primary research question is, "Is there a relationship among muscle strength, power, electromyography (EMG), mechanomyography (MMG), and muscle fiber type?" Or, "Can EMG and/or MMG be used to predict muscle fiber type?"

Hypotheses, introduction, definition of terms, and literature review:

Based on previous studies (11, 12) we hypothesize that there will be a significant relationship between MMG and muscle fiber type. No previous studies, however, have examined the relationship among muscle fiber type, EMG, and MMG during static (no movement) and isokinetic (constant velocity) muscle contractions. Previous studies have suggested that MMG can be used to differentiate among muscles that are composed of different fiber types. If the MMG signal can be used in this way, further studies must be conducted, such as this one, to examine this possibility and its limitations.

Definition of terms:

Muscle strength: The amount of force produced by a muscle or group of muscles.

Muscle power: The amount of power produced by a muscle, which can be mathematically defined as (muscle strength x distance traveled) / time.

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Mechanomyography (MMG): The recording of vibrations produced by contracting muscle fibers. MMG is recorded by miniture accelerometers placed on the surface of the skin.

Electromyography (EMG): The recording of the neural activation of contracting muscle fibers from the surface of the skin (very similar to electrocardiography [ECG] of the heart).

Static contractions: Muscle contractions that produce force around a joint with no movement (aka, isometric contractions).

Dynamic contractions: Muscle contractions that produce force around a joint while also moving a body part or limb.

Biodex System 3 dynamometer: An expensive machine that is designed to measure muscle strength and power during static and dynamic contractions (for most of the muscles in the body). In this study, we plan to use this machine to measure muscle strength and power for leg extension exercises. A spec sheet for the Biodex System 3 dynamometer is attached and can be accessed at the Biodex website (http://www.biodex.com/rehab/multi_joint/multi_joint_835feat.htm).

Isokinetic contractions: Muscle contractions that produce force at a pre-set velocity/speed (i.e., isokinetic contractions also fall under the classification of "dynamic contractions"). These types of contractions can only be done on an isokinetic dynamometer, which is typically used in a clinical rehabilitative or research setting. The Department of Kinesiology has a Biodex System 3 isokinetic dynamometer that is used for research purposes.

10. Describe the research design.

This study is one part of a collaborative research effort between The University of Texas Southwestern Medical Center at Dallas, Institute for Exercise and Environmental Medicine, Presbyterian hospital at Dallas, and The University of Texas at Arlington, Department of Kinesiology. Attached is a Project Summary entitled "Satellite cell response to resistance exercise in healthy human skeletal muscle" written by Dr. Tanja Taivassalo of the UT-Southwestern Medical Center. The Consent Form for her study is also attached. Both the Project Summary and the Consent Form are currently being reviewed by the UT-Southwestern Medical Center Institutional Review Board. Documentation of their approval will be provided.

NOTE: Only the static and dynamic muscle contractions, EMG, and MMG testing (see definitions above for explanations of these tests) will take place in the Muscle Physiology Laboratory (ESRL Rm 154) in the Exercise Research Laboratories (ESRL) facility located in the Activities Building on the UTA campus. This testing done at UTA, under the direction of Dr. Joel T. Cramer, will be non-invasive, exercise-based testing. Furthermore, this testing will occur on or before Day 0 (see the "Timeline for physiological and biopsy assessment" in the Project Summary written by Dr. Taivassalo) and will occur before any of the testing conducted at the Institute for Exercise and Environmental Medicine, UT-Southwestern Medical Center, as described in the attached Project Summary and Consent Form.

One laboratory trial, lasting no more than 1 hour, will be scheduled for each subject. In the laboratory (ESRL Rm 154) prior to each trial, EMG and MMG recording devices will be placed on the surface of the skin over the vastus lateralis (VL), rectus femoris (RF), and vastus medialis (VM) muscles of the dominant leg (as determined by kicking preference). In order to place the recording devices (very similar to ECG electrodes), the local area of the skin will be cleaned with

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alcohol and lightly exfoliated with emery paper (to remove any dead skin). Sterile electrodes will then be taped to the cleaned area. There will be nine total EMG electrodes and three total MMG sensors placed on the subjects leg. Two EMG electrodes will be placed over each muscle (VL, RF, and VM) and three EMG electrodes place over the boney area of the hip (as reference electrodes, one for each bipolar arrangement over each muscle). The three MMG sensors will be taped to the skin between each of the two EMG electrodes placed over the VL, RF, and VM muscles. This procedure is consistent with our previous studies (2-10, 14).

After the electrodes have been attached, each subject will complete a 5-minute warm-up on a stationary bicycle (Monark 818E, Sweden) at a light resistance (30-50 Watts) and a moderate cadence (60-70 rpms). Following the warm-up, two 6-second static contractions called "maximal voluntary contractions (MVC)" of the dominant leg will be measured using a Biodex System 3 isokinetic dynamometer (Biodex Medical Systems, Inc., Shirley, New York) at a knee joint angle of 60 degrees below the horizontal plane. Two or three practice contractions will be given prior to each maximal contraction. Following the static MVCs, each subject will be asked to complete three randomly ordered static contractions (at the same joint angle) at 25, 50, and 75% of the highest recorded MVC. These submaximal MVCs will each be performed twice for a duration of 6-seconds. Following the static contractions, the dynamic contractions will be performed with the same limb at slow, medium, and fast contraction speeds that are pre-set and controlled by the Biodex dynamometer. Two or three practice contractions will be given prior to the maximal contractions. A two-minute rest period will be allowed between each static and dynamic testing phase. The subjects will be in a seated position with restraining straps over the pelvis and trunk in accordance with the Biodex User's Guide (Biodex Pro Manual, Applications/Operations. Biodex Medical Systems, Inc., Shirley, NY.).

11. List potential benefits that may accrue to the study subjects as a result of their participation.

The main benefit subjects will receive from the study is feedback on their level of muscular strength and power.

12. List potential benefits that may accrue to society as a result of this study.

Society may benefit from this study through a better understanding of neuromuscular function. These findings may be useful for researchers and practitioners in the allied health professionals who may consider using surface EMG and/or MMG as potential diagnostic tools.

13. What are you and your research team's relevant qualifications to perform this research? If applicable, include information about relevant licenses / medical privileges.

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See the curriculum vitae attached.
See reference list for previously published articles (2-10, 14).

14. CHECK ALL RESEARCH PROCEDURES INVOLVING HUMAN SUBJECTS:

Any materials presented to the research subject (oral or written) may not ask of the subject to provide information about another human being who has not undergone the informed consent process (this includes the immediate family of the subject).

☐ **Collection of Blood** *State below the methods of collection (i.e. venipuncture, arterial puncture, etc.) Attach IRB Form #5 if a Tissue Repository is needed.*

☐ **Collection of Other Bodily Materials** *State below the methods of collection. Please attach IRB Form #5 if a Tissue Repository is needed.*

☐ **Analysis of Existing Data**

☐ **Cognitive or Perceptual Experiment**

☐ **Evaluation of a Program or Services** *State below whether it is Federal, State, Local, or 'Other'.*

☐ **Interview** *State below whether it is oral or written and attach a finalized copy.*

☐ **Questionnaire or Survey** *Attach a finalized copy*

☒ **Induction of Mental or Physical Stress**

☐ **Use of Private Health Information** *State below the method for obtaining this data*

☐ **Audio/Video recording of subjects**

☐ **Use of Genomic DNA or cDNA**

☐ **Use of Infectious or Carcinogenic Materials**

☐ **Educational Test or Educational Materials (curriculum, books, etc.)** *Attach copies or describe in detail*

☐ **Observation of Public Behavior with PI Participation**

☐ **Observation of Public Behavior without PI Participation**

☐ **Analysis of Existing Biological Specimens** *State below where the samples were obtained from, where they will be kept and for how long, and who will have access to them.*

☐ **Deception** *State below the debriefing procedures used*

☐ **Taste Test**

☒ **Medical Procedures** *(e.g. drug, device, radiation, surgery, non-surgical manipulation, non-invasive physical measurements, etc.)*

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☐ **Materials Commonly Regarded as Socially Unacceptable**

☐ **Use of Identified Data/Specimens**

☐ **Use of Coded Data/Specimens**

☐ **Use of Recombinant DNA** ***Attach a copy of the IBC application for rDNA along with this submission to the IRB***

☐ **Use of Biohazardous Materials**

☐ **Psychological Test** ***Attach Applicable copies or describe in detail***

14a. Please describe, in sufficient detail, the procedures for any checked items above. If you need more space, you may attach a separate sheet of paper.

NOTE: The following information is the same as the description in Section 10 and provides a detailed account for the procedures that each subject will experience.

One laboratory trial, lasting no more than 1 hour, will be scheduled for each subject. In the laboratory (ESRL Rm 154) prior to each trial, EMG and MMG recording devices will be placed on the surface of the skin over the vastus lateralis (VL), rectus femoris (RF), and vastus medialis (VM) muscles of the dominant leg (as determined by kicking preference). In order to place the recording devices (very similar to ECG electrodes), the local area of the skin will be cleaned with alcohol and lightly exfoliated with emery paper (to remove any dead skin). Sterile electrodes will then be taped to the cleaned area. There will be nine total EMG electrodes and three total MMG sensors placed on the subjects leg. Two EMG electrodes will be placed over each muscle (VL, RF, and VM) and three EMG electrodes place over the boney area of the hip (as reference electrodes, one for each bipolar arrangement over each muscle). The three MMG sensors will be taped to the skin between each of the two EMG electrodes placed over the VL, RF, and VM muscles. This procedure is consistent with our previous studies (2-10, 14).

After the electrodes have been attached, each subject will complete a 5-minute warm-up on a stationary bicycle (Monark 818E, Sweden) at a light resistance (30-50 Watts) and a moderate cadence (60-70 rpms). Following the warm-up, two 6-second static contractions called "maximal voluntary contractions (MVC)" of the dominant leg will be measured using a Biodex System 3 isokinetic dynamometer (Biodex Medical Systems, Inc., Shirley, New York) at a knee joint angle of 60 degrees below the horizontal plane. Two or three practice contractions will be given prior to each maximal contraction. Following the static MVCs, each subject will be asked to complete three randomly ordered static contractions (at the same joint angle) at 25, 50, and 75% of the highest recorded MVC. These submaximal MVCs will each be performed twice for a duration of 6-seconds. Following the static contractions, the dynamic contractions will be performed with the same limb at slow, medium, and fast contraction speeds that are pre-set and controlled by the Biodex dynamometer. Two or three practice contractions will be given prior to the maximal contractions. A two-minute rest period will be allowed between each static and dynamic testing phase. The subjects will be in a seated position with restraining straps over the pelvis and trunk in accordance with the Biodex User's Guide (Biodex Pro Manual, Applications/Operations. Biodex Medical Systems, Inc., Shirley, NY.).

14b. If the proposed research <u>is limited to</u> the use of discarded materials or retrospective chart review and there are no identifiers associating the specimens or chart information with the donors, skip sections D through G. However, if the donors can be identified, fill out section D and then skip to section H.

SECTION D: STUDY POPULATION

15. Please indicate which, if any, of the following are involved:

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☐ **UTA Staff**

☐ **UTA Faculty**

☐ **UTA Students**

☐ **Non-English Speaking People** ***Attach the consent form and all applicable materials in the native language(s) of the subjects in the research***

☒ **Adults competent to consent for themselves (non-UTA)**

☐ **Mentally Incapacitated** ***Attach IRB Form #2A***

☐ **Children** ***(Ages 0-17 years) Attach IRB Form #2D***

☐ **Pregnant Women, Fetuses, or In Vitro Fertilization** ***Attach IRB Form#2C***

☐ **Prisoners** ***Attach IRB Form #2C***

16. Total number of subjects

Dr. Taivassalo, and her staff, of the UT-Southwestern Medical Center are responsible for recruting nine (9) healthy subjects for this study. It is anticipated, therefore, that 9 healthy sedentary (not actively participating in regular physical exercise) subjects will participate in this study.

17. Subject recruitment. Please summarize your explanation of how you will recruit subjects. Include location of recruitment and enrollment. ***Please attach a copy of all recruitment flyers and ads.***

Subjects will be recruited initially from flyers placed at Presbyterian Hospital of Dallas and University of Texas Southwestern Medical Center informing potential subjects of the study and requesting potential subjects to call if they are interested. If necessary, newspaper advertisements will be purchased if the need for more subjects remains after the aforementioned options are exhausted. Initial subject contact will be performed by one of the investigators over the telephone. Interested individuals will be invited into the laboratory where the research nurse will have the subject read the Institutionally-approved consent form.

All aspects of the study will be described in detail to each subject by one of the investigators, and each subject will be provided a copy of the consent form to read and formulate any questions or concerns prior to obtaining consent. All consent forms will be maintained in the subject's charts in the Neuromuscular Office at the Institute for Exercise and Environmental Medicine.

NOTE: This information taken from the attached Project Summary written by Dr. Taivassalo of the UT-Southwestern Medical Center.

Examples of subject recruitment:
☐ **Direct person- to person solicitation per consent form.**
☐ **Telephone (attach oral presentation)**
☐ **Letter (attach finalized copy)**
☒ **Notices (attach finalized copy)**
☐ **Internet (attach finalized copy)**
☐ **Subject pool**

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☐ **Other (explain and / or attach finalized copy if applicable)**

17a. List all criteria for including subjects.

Criteria for Inclusion of Subjects: Healthy sedentary individuals of all gender, race, and ethnic background are invited to participate in this study. "Sedentary" will be defined as not having participated in any strength weight training in the past 4 weeks. Individuals are asked to refrain from engaging in other treatment studies and physical activity programs for the duration of this study. Only subject who speak, read, and write in English will be recruited for this study.

17b. List all criteria for excluding subjects.

Criteria for Exclusion of Subjects: Individuals will be excluded from participating in this study if they have any contraindication to exercise, cardiovascular, lung, neuromuscular disease, high blood pressure. Individuals under the age of 18 and over the age of 60 are excluded because these data will be used in interpreting results from our mitochondrial myopathy study of which the patients are within the age range of 18 to 60. Individuals who do not understand what is written in the Consent Form may not be eligible. In addition, individuals may be excluded from this study if their native language is not English and they are not able to read or sign the Consent Form written in the English laguage.

NOTE: These inclusion and exclusion criteria match those of Dr. Taivassalo as we will use the same subjects.

18. What rewards, remuneration, or other incentives, if any, will be used to recruit subjects?

Subjects will receive no compensation for participation in the study.

19. If the subject is a student who is undergoing this research for a course credit, how will you ensure that the subject was not coerced into participating?

UTA students will not be specifically recruited for this study.

20. Will you allow alternatives to the participation in the research without negative consequences? N/a.

SECTION E: CONFIDENTIALITY – PRIVACY – COERCION

21. Does this activity utilize data collected for other purposes? (e.g. student record, student assessments, patient records, etc.) (If this is for a data repository, please complete and attach an IRB Form #5 as well as a Consent Form for Data Repositories)

☐ **YES** ☒ **NO**

a. If yes, please specify the source of data to be utilized and how the data will be retrieved and reviewed.

b. Could any of the recorded data contain personal or sensitive information? If yes, how do you propose to code and where will you maintain confidentiality of the data?

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(Any subject data (including documents, audio, and videotapes) developed for or used by a human subject investigation protocol are potentially sensitive and must be maintained with confidentiality. All identifiable data are to be kept in a designated locked file. Sharing of identifiable data with other institutions, agencies, or companies must be identified prospectively to both the IRB and the subjects of the study.)

22. **Could any part of this activity result in the potential identification of child abuse, elderly abuse, communicable diseases, or criminal activities that would / could not have been otherwise identified? If yes, estimate the likelihood of disclosure and describe the plan of action that you will take if this occurs.** ***In rare circumstances when research reveals these issues, confidentiality should be maintained to the extent that the law allows.***

☐ **YES** ☒ **NO**

23. **Does any part of this activity have the potential for coercion of the subject? If yes, explain and describe proposed safeguards.**

☐ **YES** ☒ **NO**

24. **Please explain how you plan to maintain confidentiality. Include where your signed consent forms and identifiable data, if applicable, will be kept (under lock and key) and who will have access.**

All data will be kept by the investigators in a locked file. All participants will receive identifying numbers and only the investigators will be able to identify individuals. All data will be compiled and only group data will be used for dissemination.

SECTION F: RISKS - PSYCHOLOGICAL RISKS

25. **Aside from possible loss of confidentiality, is there a possibility of psychological injury resulting from participating in the research?**

☐ **YES** ☒ **NO**

26. **If you answered yes, how do you plan to minimize and control the risks?**

27. **Could the desired information be obtained from animals or other laboratory models? Explain.**

☐ **YES** ☒ **NO**

In the event of an adverse event, you must fill out the IRB Form #8 to report the event to the Institutional Review Board for the protection of human subjects <u>immediately</u>.

SECTION G: RISKS - PHYSICAL RISKS

28. **Is there a possibility of physical injury resulting from participation in the research?**

☒ **YES** ☐ **NO**

29. **If you answered yes, how do you plan to minimize and control the risks?**

The subjects may experience muscle soreness and temporary elevation of blood pressure during

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the isokinetic tests. To minimize these risks, subjects will perform a warm-up exercise on a cycle ergometer prior to the isometric and isokinetic tests. Furthermore, subjects will be given instructions for special stretches, which may aid in the elimination of any muscle soreness as a result of the tests. Throughout the tests, subjects will be monitored by laboratory personnel trained in CPR. In addition, the subjects will be asked repeatedly during the tests how they feel in relation to their ability to continue the test.

Though unlikely, there is a slight possibility of infection and soreness from skin exfoliations for the electrode placements. Upon completion of all tests, an antibacterial salve will be applied to the electrode exfoliation sites to prevent any possible infection.

30. Could the desired information be obtained from animals or other laboratory models? Explain.

☐ **YES** ☒ **NO**

In the event of an adverse event, you must fill out the IRB Form #8 to report the event to the Institutional Review Board for the protection of human subjects immediately.

SECTION H: COST OF RESEARCH

31. Will the subjects incur any additional expenses for experimental (or otherwise unnecessary diagnostic) tests or procedures? If yes, explain

☐ **YES** ☒ **NO**

32. Is there any charge to the participant for participation? If yes, explain.

☐ **YES** ☒ **NO**

SECTION I: INFORMED CONSENT

33. Written, informed consent from the subject or from a legally responsible representative of the subject is normally required from the human research participants. The finalized consent form in all applicable languages should be included with the materials submitted to the IRB. You must keep all signed consent forms under lock and key during the study and for a period of 3 years after termination of the research on UTA Campus. These consent forms are subject to inspection by the Research Compliance Officer, the IRB and / or DHHS.

If you do not plan to obtain consent or written documentation of consent, please attach a completed IRB Form # 3.

a. If appropriate, describe your rationale for obtaining oral consent or assent instead of written consent. Attach a copy of the information to be read and given to the subjects.

b. Do you plan to make consent forms available in the native language for all subjects involved in the research? Please explain your procedures in determining the primary language spoken by the subjects and how you plan to deliver the informed consent process to subjects who do not speak English.

☐ **YES** ☒ **NO**

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SECTION J: COOPERATIVE AGREEMENTS WITH OTHER INSTITUTIONS

34. If any part of this study will be conducted in an institution or location administratively separate from UTA, please indicate at which institution (attach an approval letter).

The University of Texas Southwestern Medical Center at Dallas, Institute for Exercise and Environmental Medicine, Presbyterian hospital at Dallas. An IRB approval letter is attached.

a. Does this activity utilize recorded data to be sent to cooperating institutions, or agencies not under your control?

☒ **YES** ☐ **NO**

b. If yes, could the data contain personal or sensitive information or put the participant in any type of legal risk?

No. If any information of the subjects is sent to cooperating institutions or agencies not under the principle investigator's control, it will be non-personal or non-sensative in nature. In addition, all participants will receive identifying numbers, and only the investigators will be able to identify individuals. Outside institutions or agencies will only be allowed access to the identification numbers and will not be able to identify individuals.

c. If yes, how do you propose to maintain the confidentiality of the data?

SECTION K: CONSULTATION AND COLLABORATION

35. Subject recruitment and management:
If approval is required from other professionals for the recruitment and management of the subjects, please identify and obtain signature(s) from the individual(s) responsible for the subjects. If unobtainable, please explain or attach a signed agreement or letter.

Name of Professional	Department	Signature	Date
1. Dr. Tanja Taivassalo	The University of Texas Southwestern Medical Center at Dallas, Institute for Exercise and Environmental Medicine, Presbyterian hospital at Dallas	(see letter attached)	
2.			
3.			

36. Research collaboration:

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Research collaborators are other researchers whose participation enhances the scientific merit of a research project. Have all collaborators indicate by signing this document that they have read the research protocol and agree to participate. If unobtainable, please explain or attach a signed agreement or letter.

Name of Collaborator	Department	Signature	Date
1. Dr. Tanja Taivassalo	The University of Texas Southwestern Medical Center at Dallas, Institute for Exercise and Environmental Medicine, Presbyterian hospital at Dallas	(see letter attached)	
2.			
3.			

SECTION L: CONFLICT OF INTEREST DISCLOSURE

37. **Have you submitted a financial disclosure statement to your department chair listing all of your significant financial interests in accordance with The University of Texas at Arlington conflict of interest policy?**

☒ **YES** ☐ **NO**

38. **Did your department chair find that there was a potential conflict of interest and did he/ she forward the statement to the Dean and / or the Vice Presi dent for Research and Information Technology?**

☐ **YES** ☒ **NO**

39. **If yes, please explain the conditions and restrictions imposed. If the conflict of interest is still pending review, please indicate here.**

☐ **YES** ☒ **NO**

40. **Did your department chair forward the original statement to the Office of Research?**

☒ **YES** ☐ **NO**

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SECTION M: SIGNATURES

I understand that I am responsible for the accuracy of the statements made in this protocol and for the conduct of research.

I understand that I am to submit annual reviews to the Institutional Review Board for the Protection of Human Subjects. If the annual report (IRB FORM # 6) has not been received by the IRB Chair (or designee) by the anniversary date of the approval, this protocol's approval is terminated.

I understand that I am to file a final report upon conclusion of the research with the Institutional Review Board for the Protection of Human Subjects (IRB FORM # 7).

I understand that if my research is under a sponsored research agreement, additional standards may apply.

I am aware that upon approval of this protocol, the Research Compliance Officer may request to be present during at least one of my informed consent procedures on my Human Subjects.

I am aware that the signed consent forms need to be filed under lock and key during the research and for a period of 3 years upon termination of the research (if unfunded). For funded research, the consent forms will be kept for the length established under the terms and conditions of the award. These consent forms will be available for inspection by the Research Compliance Officer, the UTA IRB, or agents from Federal Agencies.

I understand that I, as well as all Human Subject Investigators involved in this study, must have documented Human Subject training in the Office of Research before performing any Human Subject research.

_____ _____
Principal Investigator **Date**

I have examined this completed form and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of Human Subjects. I will take responsibility for informing the student of the need for safekeeping of all raw data (e.g. test protocols, tapes, questionnaires, interview notes, etc.) in a university office or computer file. I will be responsible to see that all consent documents are stored on UTA campus in a locked file during the research and 3 years after the conclusion of the research. I will be responsible to see that all Annual and Final Reports (IRB Form #7) are submitted to the IRB by the anniversary date(s) of the approval and upon conclusion of the research (conclusion of data analysis.)

_____ _____
Faculty Sponsor (If not the Principal Investigator) **Date**

I have read this completed form and endorse this research to be conducted.

_____ _____
Department Chairman or Dean or Director Date