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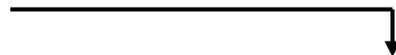
Section 1: General Information

1.1 DO ANY OF THE INVESTIGATORS OF THIS PROJECT HAVE A REPORTABLE CONFLICT OF INTEREST? (<http://www.irb.vt.edu/pages/researchers.htm#conflict>)

- No
 Yes, explain:

1.2 IS THIS RESEARCH SPONSORED OR SEEKING SPONSORED FUNDS?

- No, go to question 2.1
 Yes, answer questions within table



IF YES
Provide the name of the sponsor [if NIH, specify department]:
<p>Is this project receiving or seeking federal funds?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>If yes,</p> <p>Does the grant application, OSP proposal, or “statement of work” related to this project include activities involving human subjects that are <u>not</u> covered within this IRB application?</p> <p><input type="checkbox"/> No, all human subject activities are covered in this IRB application <input type="checkbox"/> Yes, however these activities will be covered in future VT IRB applications, these activities include: <input type="checkbox"/> Yes, however these activities have been covered in past VT IRB applications, the IRB number(s) are as follows: <input type="checkbox"/> Yes, however these activities have been or will be reviewed by another institution’s IRB, the name of this institution is as follows: <input type="checkbox"/> Other, explain:</p> <p>Is Virginia Tech the primary awardee or the coordinating center of this grant?</p> <p><input type="checkbox"/> No, provide the name of the primary institution: <input type="checkbox"/> Yes</p>

Section 2: Justification

2.1 DESCRIBE THE BACKGROUND, PURPOSE, AND ANTICIPATED FINDINGS OF THIS STUDY:

Shoulder and neck pain is becoming increasingly common in office workers. Some research suggests that there are somatic differences in the way that workers who suffer from shoulder and neck pain work,

when compared to their healthy counterparts. Muscle variability has been shown to reduce fatigue and increase endurance, however, these results have been shown in mostly static, isometric tasks. This study will look at a simulated office task, in which muscle activity, posture and subjective assessment will be measured. The hypothesis is: There is a measurable difference in the muscle variation between healthy workers and workers with chronic neck and shoulder pain, which can be shown using exposure variation analysis (EVA). EVA is a tool in physical ergonomic studies used to quantify the variation in tasks based on the intensity and frequency of biomechanical exposures (muscle activity in our study).

If we do find the hypothesized differences in muscle activity variation between the pain group and the healthy group during the performance of computer work, this can be used as a diagnostic tool to evaluate the effects of future interventions aimed at alleviating chronic neck-shoulder pain in office workers.

2.2 EXPLAIN WHAT THE RESEARCH TEAM PLANS TO DO WITH THE STUDY RESULTS:

For example - publish or use for dissertation

The research team plans to use these results for a Masters thesis work and publish these results in peer-reviewed journals and/or conference proceedings.

Section 3: Recruitment

3.1 DESCRIBE THE SUBJECT POOL, INCLUDING INCLUSION AND EXCLUSION CRITERIA AND NUMBER OF SUBJECTS:

Examples of inclusion/exclusion criteria - gender, age, health status, ethnicity

Up to 24 participants, 12 per group, will be sought from the university population and local community including VT students, from among individuals aged 18-45 years, and engaged in self-reported computer use for an average of at least 4 hours a day for at least the last 2 years. Healthy female and male participants that have not reported any musculoskeletal, neurological or cardiovascular disorders; and have not had pain in their neck-shoulder, upper extremities and low-back for at least 1 year before testing will be recruited in the healthy control group. Female and male participants with neck-shoulder pain will be included in the pain group according to standardized procedures used in previous research: i.e. if they have experienced pain in their neck or shoulder region of the dominant upper extremity for at least 30 days in the last 1 year, have perceived pain of intensity greater than 2 on a scale of 0 to 10 at least once a week in the last 3 months, and do not have any diagnosed systemic diseases, widespread or neurological pain conditions such as fibromyalgia or migraines (see attached questionnaires for more details). No potential participants will be excluded based on gender or ethnicity.

3.2 WILL EXISTING RECORDS BE USED TO IDENTIFY AND CONTACT / RECRUIT SUBJECTS?

Examples of existing records - directories, class roster, university records, educational records

No, go to question 3.3

Yes, answer questions within table

IF YES

Are these records private or public?

Public

Private, describe the researcher's privilege to the records:

Will student, faculty, and/or staff records or contact information be requested from the University?

No

Yes, provide a description under Section 14 (Research Involving Existing Data) below.

3.3 DESCRIBE RECRUITMENT METHODS, INCLUDING HOW THE STUDY WILL BE ADVERTISED OR INTRODUCED TO SUBJECTS:

We will recruit for participants through advertisement in the form of ads distributed as flyers or by email (see ad submitted with the application).

3.4 PROVIDE AN EXPLANATION FOR CHOOSING THIS POPULATION:

Note: the IRB must ensure that the risks and benefits of participating in a study are distributed equitably among the general population and that a specific population is not targeted because of ease of recruitment.

The subjects will be recruited from Virginia Tech and the greater community and are expected to be reasonably representative of the general population. The age limit for participation is limited at 45 years since we expect aging to have confounding effects on the biomechanical properties assessed in this study. A minimum computer use time is required for participation as the effects being investigated here are relevant in general to those engaged in computer-intensive office work, and we'd like our study participants to be representative of this general population. Inclusion and exclusion criteria for the pain group are based on published research on chronic pain conditions in the neck-shoulder region that affect performance of routine computer-based office work.

Section 4: Consent Process

For more information about consent process and consent forms visit the following link: <http://www.irb.vt.edu/pages/consent.htm>

If feasible, researchers are advised and may be required to obtain signed consent from each participant unless obtaining signatures leads to an increase of risk (e.g., the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting in a breach of confidentiality). Signed consent is typically not required for low risk questionnaires (consent is implied) unless audio/video recording or an in-person interview is involved. If researchers will not be obtaining signed consent, participants must, in most cases, be supplied with consent information in a different format (e.g., in recruitment document, at the beginning of survey instrument, read to participant over the phone, information sheet physically or verbally provided to participant).

4.1 CHECK ALL OF THE FOLLOWING THAT APPLY TO THIS STUDY'S CONSENT PROCESS:

- Verbal consent will be obtained from participants
- Signed consent will be obtained from participants
- Consent will be implied from the return of completed questionnaire. Note: The IRB recommends providing consent information in a recruitment document or at the beginning of the questionnaire (if the study only involves implied consent, skip to Section 5 below)
- Other, describe:

4.2 PROVIDE A GENERAL DESCRIPTION OF THE PROCESS THE RESEARCH TEAM WILL USE TO OBTAIN AND MAINTAIN INFORMED CONSENT:

Participants will be asked for their consent after the study is fully described to them by the researchers, including the purpose of the study, study procedures, the time commitment required, relevant instrumentation and a demonstration of the experimental tasks involved, and after all questions from the participants regarding the study have been answered. Consent will be obtained prior to any data collection.

4.3 WHO, FROM THE RESEARCH TEAM, WILL BE OVERSEEING THE PROCESS AND OBTAINING CONSENT FROM SUBJECTS?

Divya Srinivasan, Sunwook Kim, Denean Kelson

4.4 WHERE WILL THE CONSENT PROCESS TAKE PLACE?

In the test laboratory, located at 539 Whittemore Hall (Safety Lab)

4.5 DURING WHAT POINT IN THE STUDY PROCESS WILL CONSENTING OCCUR?

Note: unless waived by the IRB, participants must be consented before completing any study procedure, including screening questionnaires.

Participants will be asked if they consent to the study and sign the informed consent form after the study is fully described to them and all their questions regarding the study have been answered. This process will occur before any instrumentation or pilot testing or data collection has begun.

4.6 IF APPLICABLE, DESCRIBE HOW THE RESEARCHERS WILL GIVE SUBJECTS AMPLE TIME TO REVIEW THE CONSENT DOCUMENT BEFORE SIGNING:

Note: typically applicable for complex studies, studies involving more than one session, or studies involving more of a risk to subjects.

A copy of the consent form will be provided to potential participants at least 24 hours ahead of time, so that they have time to review the consent form before arriving at the lab for participation. In addition, once they arrive in the lab for participation, there will be an additional opportunity for them to go through the consent form in detail, there will be no time limit given to potential participants for them to understand whether they would like to participate in the study, and convey their willingness by consenting to participate. They can ask any questions they may have about the experiment at any time to the researchers for further clarification.

Not applicable

Section 5: Procedures

5.1 PROVIDE A STEP-BY-STEP THOROUGH EXPLANATION OF ALL STUDY PROCEDURES EXPECTED FROM STUDY PARTICIPANTS, INCLUDING TIME COMMITMENT & LOCATION:

We propose a repeated measures design. We will use healthy participants, as well as, participants with neck and shoulder pain. Patients with pain will be asked to complete one session while their healthy counterparts will complete two repeated sessions. For each session, we will quantify movement kinematics and muscle activations in the neck-shoulder region using posture recordings of the head, upper arms and trunk, and surface electromyography from neck-shoulder muscles, and heart rate using a heart rate monitor. A same-sex experimenter will be available for both male and female participants to assist with placing sensors and electrodes on participants' clothing and skin. Participants' will be required to wear a tank top during experiment, and we will provide them with one if they do not have one. In between sessions, the experimenters will be responsible for washing and cleaning the tank top for repeated use. In addition, discomfort will be assessed through use of a perceived discomfort rating.

Procedures:

- 1. The study background and procedures will be explained to the participants and informed consent obtained;**
- 2. Following this, demographic information, pain questionnaire and basic anthropometric information will be asked verbally, through written questionnaires and/or measured non-invasively (see attached baseline questionnaire);**
- 3. Researchers will attach surface electromyography (EMG) electrodes on skin corresponding to neck-shoulder and hand-arm muscles (e.g. trapezius, deltoids, forearm flexors and extensors) and inertial motion sensors for measuring head, upper extremity and trunk body postures; and the heart rate monitor (all on surface and non-invasive);**
- 4. Participants will perform isometric reference voluntary contractions using standardized weights to normalize task-related muscle activity data in each instrumented muscle group. These contractions will involve lifting a standardized weight of 1-2 lbs for about 10-15 seconds.**
- 5. The participant will be asked to rate the current level of discomfort in different parts of their body (e.g. neck-shoulder, low-back etc using the attached "discomfort" questionnaire);**
- 6. Perform general computer-based office tasks for 60 minutes in a continuous seated posture. The participants will be asked to perform keyboard tasks (typing), mouse-use tasks (pointing, clicking and dragging) and combinations of keyboard and mouse tasks, common in everyday computer use. Prior to**

the experiment, all participants will be trained for a period of 15 minutes, on the kinds of tasks that they will perform, and any questions they have about task types/work pace etc will be answered during this training phase. Participants will work at an average/comfortable pace. Participants will be use the standardized workstation set up in the laboratory (i.e. standard keyboard, mouse and monitor provided by experimenters), so that all users use the same computer-input/output devices;

7. At the end of 60 minutes of work, the participant will be asked to rate the current level of discomfort in different parts of their body using the same "discomfort" questionnaire as they did at the start of the task;

8. Finally, all instrumentation will be removed from the participant. The tank tops provided will be washed between participants.

The participants in the pain group will complete only one session while the participants in the healthy group will return to the lab for a second test session where the exact same procedures will be repeated. This is in order to estimate the reliability of the metrics that will be used to quantify variation in this study. Sessions will be completed on different days, with at least 2 days in between and not more than 2 weeks, in order to allow for sufficient rest.

Each experimental session will take at most 120 minutes including questionnaires, instrumentation, training and work tasks, and the study will be performed in the Safety Lab (Whittemore 539).

5.2 DESCRIBE HOW DATA WILL BE COLLECTED AND RECORDED:

Basic demographic (age and gender), anthropometric (stature, body weight, bottom to pelvis height, popliteal height, and elbow rest height) and pain related information will be obtained verbally and through non-invasive measurements if necessary (see attached "baseline questionnaire"). These will be recorded both manually and to a spreadsheet program by the investigators. During the office work task, muscle activity, postures and heart rate will be recorded using surface electromyography, inertial-based posture recording systems and a heart rate monitor. Perceived discomfort will be obtained using a standard questionnaires (attached in the appendix as the "discomfort" questionnaire).

All sensors for objective measures will be synchronized using custom data acquisition software installed in a password-protected computer.

5.3 DOES THE PROJECT INVOLVE ONLINE RESEARCH ACTIVITES (INCLUDES ENROLLMENT, RECRUITMENT, SURVEYS)?

View the "Policy for Online Research Data Collection Activities Involving Human Subjects" at <http://www.irb.vt.edu/documents/onlinepolicy.pdf>

- No, go to question 6.1
 Yes, answer questions within table

IF YES

Identify the service / program that will be used:

- www.survey.vt.edu, go to question 6.1
 SONA, go to question 6.1
 Qualtrics, go to question 6.1
 Center for Survey Research, go to question 6.1
 Other

IF OTHER:

Name of service / program:

URL:

This service is...

- Included on the list found at: <http://www.irb.vt.edu/pages/validated.htm>
 Approved by VT IT Security
 An external service with proper SSL or similar encryption (https://) on the login (if applicable) and all other data collection pages.
 None of the above (note: only permissible if this is a collaborative project in which VT individuals are only responsible for data analysis, consulting, or recruitment)

Section 6: Risks and Benefits

6.1 WHAT ARE THE POTENTIAL RISKS (E.G., EMOTIONAL, PHYSICAL, SOCIAL, LEGAL, ECONOMIC, OR DIGNITY) TO STUDY PARTICIPANTS?

The study has no more than minimal risk involved. It does not introduce any more risk than what participants are exposed to on a daily basis. The participants will perform computer-based office work for ~1 hour. This is not expected to cause any discomfort for the healthy or the pain group.

The measurement systems are all non-invasive and hence not intrusive. Some participants may experience minor irritation from the skin preparation prior to mounting surface electromyography (EMG) electrodes (e.g., cleaning the skin with sand paper and rubbing alcohol) and removal of the electrodes used to record muscle activity.

6.2 EXPLAIN THE STUDY'S EFFORTS TO REDUCE POTENTIAL RISKS TO SUBJECTS:

Participants with pain will only complete session, while healthy will complete two repeated sessions. Also, each session will only last ~1 hour in order to not induce significant discomfort.

Only noninvasive surface EMG electrodes will be used for measuring muscle activities, and the sandpaper will only be used to clean the surface of the skin to remove dead skin cells. In addition to reducing no more than minimal risk to participants, researchers will emphasize that participants can terminate participation at any time without any further explanation or penalty.

6.3 WHAT ARE THE DIRECT OR INDIRECT ANTICIPATED BENEFITS TO STUDY PARTICIPANTS AND/OR SOCIETY?

This study will provide insight on the somatic differences between workers who have and do not have pain. This will lead to further studies on how to increase variation in workers with pain, which we believe will contribute to decreased discomfort during work. No promise or guarantee of benefits will be made to participants. Participants may contact the investigators listed and the end of the consent form to inquire about the general results and conclusions of this research.

Section 7: Full Board Assessment

7.1 DOES THE RESEARCH INVOLVE MICROWAVES/X-RAYS, OR GENERAL ANESTHESIA OR SEDATION?

- No
 Yes

7.2 DO RESEARCH ACTIVITIES INVOLVE PRISONERS, PREGNANT WOMEN, FETUSES, HUMAN IN VITRO FERTILIZATION, OR INDIVIDUALS WITH MENTAL DISORDERS?

- No, go to question 7.3
 Yes, answer questions within table

IF YES

This research involves:

- Prisoners
 Pregnant women Fetuses Human in vitro fertilization

Individuals with a mental disorder

7.3 DOES THIS STUDY INVOLVE MORE THAN MINIMAL RISK TO STUDY PARTICIPANTS?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily activities or during the performance of routine physical or psychological examinations or tests. Examples of research involving greater than minimal risk include collecting data about abuse or illegal activities. Note: if the project qualifies for Exempt review (<http://www.irb.vt.edu/pages/categories.htm>), it will not need to go to the Full Board.

- No
 Yes

IF YOU ANSWERED "YES" TO ANY ONE OF THE ABOVE QUESTIONS, 7.1, 7.2, OR 7.3, THE BOARD MAY REVIEW THE PROJECT'S APPLICATION MATERIALS AT ITS MONTHLY MEETING. VIEW THE FOLLOWING LINK FOR DEADLINES AND ADDITIONAL INFORMATION: <http://www.irb.vt.edu/pages/deadlines.htm>

Section 8: Confidentiality / Anonymity

For more information about confidentiality and anonymity visit the following link: <http://www.irb.vt.edu/pages/confidentiality.htm>

8.1 WILL PERSONALLY IDENTIFYING STUDY RESULTS OR DATA BE RELEASED TO ANYONE OUTSIDE OF THE RESEARCH TEAM?

For example – to the funding agency or outside data analyst, or participants identified in publications with individual consent

- No
 Yes, to whom will identifying data be released?

8.2 WILL THE RESEARCH TEAM COLLECT AND/OR RECORD PARTICIPANT IDENTIFYING INFORMATION (E.G., NAME, CONTACT INFORMATION, VIDEO/AUDIO RECORDINGS)?

Note: if collecting signatures on a consent form, select "Yes."

- No, go to question 8.3
 Yes, answer questions within table

IF YES

Describe if/how the study will utilize study codes: A coding system will be used to associate a participant's identity with individual data.

If applicable, where will the key [i.e., linked code and identifying information document (for instance, John Doe = study ID 001)] be stored and who will have access? Participant's personal information and identity will be kept in confidence. The coding system will be used to associate their identity with individual's data. Photographs may be taken for assessment of individual's postures. However, any images used in any documentation will have the faces of participant's blacked out to maintain confidentiality and ensure that the participants cannot be identified. All individual information will be collected and stored in a file cabinet that will be locked in Dr. Srinivasan's office where only she will have access to individual-identifying information after the completion of the experiment. All data will be stored in a password-secured computers, and only the research team will have access to the data.

Note: the key should be stored separately from subjects' completed data documents and accessibility should be limited.

The IRB strongly suggests and may require that all data documents (e.g., questionnaire responses, interview responses, etc.) do not include or request identifying information (e.g., name, contact information, etc.) from

participants. If you need to link subjects' identifying information to subjects' data documents, use a study ID/code on all data documents.

8.3 HOW WILL DATA BE STORED TO ENSURE SECURITY (E.G., PASSWORD PROTECTED COMPUTERS, ENCRYPTION) AND LIMITED ACCESS?

Examples of data - questionnaire, interview responses, downloaded online survey data, observation recordings, biological samples

Data will be stored to ensure security and limited access through storage in locked cabinets and password-protected computers.

8.4 WHO WILL HAVE ACCESS TO STUDY DATA?

Only the study investigators will have access to data.

8.5 DESCRIBE THE PLANS FOR RETAINING OR DESTROYING STUDY DATA:

The list of names associated to individual data will be destroyed one month after completion of data collection. Copies of the questionnaire will be destroyed once the responses are entered into a database in password-protected computers.

8.6 DOES THIS STUDY REQUEST INFORMATION FROM PARTICIPANTS REGARDING ILLEGAL BEHAVIOR?

- No, go to question 9.1
 Yes, answer questions within table

IF YES

Does the study plan to obtain a Certificate of Confidentiality?

- No
 Yes (Note: participants must be fully informed of the conditions of the Certificate of Confidentiality within the consent process and form)

For more information about Certificates of Confidentiality, visit the following link:

<http://www.irb.vt.edu/pages/coc.htm>

Section 9: Compensation

For more information about compensating subjects, visit the following link: <http://www.irb.vt.edu/pages/compensation.htm>

9.1 WILL SUBJECTS BE COMPENSATED FOR THEIR PARTICIPATION?

- No, go to question 10.1
 Yes, answer questions within table

IF YES

What is the amount of compensation? \$10 per hour

Will compensation be prorated?

- Yes, please describe: **If participants choose to withdraw before completing the study, they will be compensated for the proportion of study time that they do complete.**
- No, explain why and clarify whether subjects will receive full compensation if they withdraw from the study?

Unless justified by the researcher, compensation should be prorated based on duration of study participation. Payment must not be contingent upon completion of study procedures. In other words, even if the subject decides to withdraw from the study, he/she should be compensated, at least partially, based on what study procedures he/she has completed.

Section 10: Audio / Video Recording

For more information about audio/video recording participants, visit the following link: <http://www.irb.vt.edu/pages/recordings.htm>

10.1 WILL YOUR STUDY INVOLVE VIDEO AND/OR AUDIO RECORDING?

- No, go to question 11.1
- Yes, answer questions within table

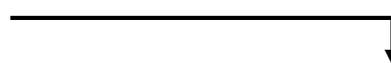


IF YES
This project involves: <input type="checkbox"/> Audio recordings only <input type="checkbox"/> Video recordings only <input type="checkbox"/> Both video and audio recordings
Provide compelling justification for the use of audio/video recording:
How will data within the recordings be retrieved / transcribed?
How and where will recordings (e.g., tapes, digital data, data backups) be stored to ensure security?
Who will have access to the recordings?
Who will transcribe the recordings?
When will the recordings be erased / destroyed?

Section 11: Research Involving Students

11.1 DOES THIS PROJECT INCLUDE STUDENTS AS PARTICIPANTS?

- No, go to question 12.1
- Yes, answer questions within table



IF YES
Does this study involve conducting research with students of the researcher? <input checked="" type="checkbox"/> No

<input type="checkbox"/> Yes, describe safeguards the study will implement to protect against coercion or undue influence for participation: <i>Note: if it is feasible to use students from a class of students not under the instruction of the researcher, the IRB recommends and may require doing so.</i>
Will the study need to access student records (e.g., SAT, GPA, or GRE scores)? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes

11.2 DOES THIS PROJECT INCLUDE ELEMENTARY, JUNIOR, OR HIGH SCHOOL STUDENTS?

- No**, go to question 11.3
 Yes, answer questions within table

IF YES
Will study procedures be completed during school hours? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, <p style="text-align: center;">Students not included in the study may view other students' involvement with the research during school time as unfair. Address this issue and how the study will reduce this outcome:</p> <p style="text-align: center;">Missing out on regular class time or seeing other students participate may influence a student's decision to participate. Address how the study will reduce this outcome:</p>
Is the school's approval letter(s) attached to this submission? <input type="checkbox"/> Yes <input type="checkbox"/> No, project involves Montgomery County Public Schools (MCPS) <input type="checkbox"/> No, explain why: <i>You will need to obtain school approval (if involving MCPS, click here: http://www.irb.vt.edu/pages/mcps.htm). Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should accompany the approval request to the IRB.</i>

11.3 DOES THIS PROJECT INCLUDE COLLEGE STUDENTS?

- No**, go to question 12.1
 Yes, answer questions within table

IF YES
Some college students might be minors. Indicate whether these minors will be included in the research or actively excluded: <input type="checkbox"/> Included <input checked="" type="checkbox"/> Actively excluded, describe how the study will ensure that minors will not be included: Only individuals 18 years of age or older will be included. We will ask for age verification, such from a current driver's license.
Will extra credit be offered to subjects? <input checked="" type="checkbox"/> No

Yes

If yes,

What will be offered to subjects as an equal alternative to receiving extra credit without participating in this study?

Include a description of the extra credit (e.g., amount) to be provided within question 9.1 (“IF YES” table)

Section 12: Research Involving Minors

12.1 DOES THIS PROJECT INVOLVE MINORS (UNDER THE AGE OF 18 IN VIRGINIA)?

Note: age constituting a minor may differ in other States.

No, go to question 13.1

Yes, answer questions within table

IF YES

Does the project reasonably pose a risk of reports of current threats of abuse and/or suicide?

No

Yes, thoroughly explain how the study will react to such reports:

Note: subjects and parents must be fully informed of the fact that researchers must report threats of suicide or suspected/reported abuse to the appropriate authorities within the Confidentiality section of the Consent, Assent, and/or Permission documents.

Are you requesting a waiver of parental permission (i.e., parent uninformed of child’s involvement)?

No, **both** parents/guardians will provide their permission, if possible.

No, **only one** parent/guardian will provide permission.

Yes, describe below how your research meets **all** of the following criteria (A-D):

Criteria A - The research involves no more than minimal risk to the subjects:

Criteria B - The waiver will not adversely affect the rights and welfare of the subjects:

Criteria C - The research could not practicably be carried out without the waiver:

Criteria D - (Optional) Parents will be provided with additional pertinent information after participation:

Is it possible that minor research participants will reach the legal age of consent (18 in Virginia) while enrolled in this study?

No

Yes, will the investigators seek and obtain the legally effective informed consent (in place of the minors’ previously provided assent and parents’ permission) for the now-adult subjects for any ongoing interactions with the subjects, or analysis of subjects’ data? If yes, explain how:

For more information about minors reaching legal age during enrollment, visit the following link:

<http://www.irb.vt.edu/pages/assent.htm>

*The procedure for obtaining assent from minors and permission from the minor’s guardian(s) must be described in **Section 4** (Consent Process) of this form.*

Section 13: Research Involving Deception

For more information about involving deception in research and for assistance with developing your debriefing form, visit our website at <http://www.irb.vt.edu/pages/deception.htm>

13.1 DOES THIS PROJECT INVOLVE DECEPTION?

- No**, go to question 14.1
 Yes, answer questions within table

IF YES
Describe the deception:
Why is the use of deception necessary for this project?
Describe the debriefing process:
Provide an explanation of how the study meets <u>all</u> the following criteria (A-D) for an alteration of consent: Criteria A - The research involves no more than minimal risk to the subjects: Criteria B - The alteration will not adversely affect the rights and welfare of the subjects: Criteria C - The research could not practicably be carried out without the alteration: Criteria D - (Optional) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception): <i>By nature, studies involving deception cannot provide subjects with a complete description of the study during the consent process; therefore, the IRB must allow (by granting an alteration of consent) a consent process which does not include, or which alters, some or all of the elements of informed consent.</i> <i>The IRB requests that the researcher use the title "Information Sheet" instead of "Consent Form" on the document used to obtain subjects' signatures to participate in the research. This will adequately reflect the fact that the subject cannot fully consent to the research without the researcher fully disclosing the true intent of the research.</i>

Section 14: Research Involving Existing Data

14.1 WILL THIS PROJECT INVOLVE THE COLLECTION OR STUDY/ANALYSIS OF EXISTING DATA DOCUMENTS, RECORDS, PATHOLOGICAL SPECIMENS, OR DIAGNOSTIC SPECIMENS?

Please note: it is not considered existing data if a researcher transfers to Virginia Tech from another institution and will be conducting data analysis of an on-going study.

- No**, you are finished with the application
 Yes, answer questions within table

IF YES
From where does the existing data originate?
Provide a detailed description of the existing data that will be collected or studied/analyzed:
Is the source of the data public? <input type="checkbox"/> No, continue with the next question <input type="checkbox"/> Yes, you are finished with this application

Will any individual associated with this project (internal or external) have access to or be provided with existing data containing information which would enable the identification of subjects:

- **Directly** (e.g., by name, phone number, address, email address, social security number, student ID number), or
- **Indirectly through study codes** even if the researcher or research team does not have access to the master list linking study codes to identifiable information such as name, student ID number, etc
or
- **Indirectly through the use of information that could reasonably be used in combination to identify an individual** (e.g., demographics)

No, collected/analyzed data will be completely de-identified

Yes,

If yes,

Research will not qualify for exempt review; therefore, if feasible, written consent must be obtained from individuals whose data will be collected / analyzed, unless this requirement is waived by the IRB.

Will written/signed or verbal consent be obtained from participants prior to the analysis of collected data? -select one-

This research protocol represents a contract between all research personnel associated with the project, the University, and federal government; therefore, must be followed accordingly and kept current.

Proposed modifications must be approved by the IRB prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects.

Do not begin human subjects activities until you receive an IRB approval letter via email.

It is the Principal Investigator's responsibility to ensure all members of the research team who interact with research subjects, or collect or handle human subjects data have completed human subjects protection training prior to interacting with subjects, or handling or collecting the data.

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