View xForm - IRB Application Form

Use this form for all new proposals submitted to the CUPIRB regardless of what category you expect the Proposal to fall under.

New Submission Data Entry - Submitted 0[redacted]

Section A: New Submission Study Details

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Saving you work. *Each time you click 'Next' or 'Previous' your work is saved. You may click 'Save for Later' to save where you are and leave the form. If you jump to another page, using the dropdown at the top of the form, your work on each page will be saved. You will not be able to 'Check and Submit' form until all required fields are entered.*

Submitter

[redacted]

Email: [redacted] **Phone:**

Study Title

Optimal Rest Time for Post-activation Potentiation (PAP) on Vertical Jump Performance

Principal Investigator

[redacted]

Expirations: Biomedical Research-Basic/Refresher - 01/03/2025 • IRB Members-Basic/Refresher - 09/19/2025

Please enter the email address for the Principal Investigator for this study. If you are the PI please enter your own email address. ***If you are a student researcher, please note that the PI must be a faculty member of Commonwealth University of Pennsylvania.*** *Once you add your email address, your contact information will populate, including your current CITI Human Subject expirations.*

Please select the Principal Investigator's Department.

[redacted]

Please provide your basic research question.

The research question for this project is what the ideal rest time is after a bout of Post-activation potentiation, via weighted vest jumps, to elicit the highest vertical jump performance. The primary variable being assessed is jump performance (height). Secondary variables being assessed include Heart Rate, Blood Lactate, and Rate of Perceived Exertion.

Please provide a brief summary for this study

There are several variables to consider that can influence PAP results. Research has yet to determine the perfect combination of exercise choice, volume, rest time, intensity, and training status to elicit the optimal PAP effect. This study will aim to discover the ideal rest time after a bout of PAP, via weighted vest jumps, to elicit the highest vertical jump performance. Recreationally active participants will be recruited from LHU's campus.

Is your research taking place On-campus or Off-campus?

On-campus

When do you anticipate starting this research?

08/21/2023

Important Notice: Please remember that you may not start your research until you have received final IRB Approval.

When do you anticipate your research will be complete?

05/17/2024

Funding Type

Unfunded Student Research

External Funding is support from an external source. Internal Funding is support from within the University.

Section B: Other Key Personnel

Section B: Other Key Personnel

All Study Personnel interacting with study participants and/or having access to identifiable data are required to be listed on this study. Please note: they are required to complete the appropriate CITI Human Subjects Training (Social & Behavioral or Biomedical Human Subject CITI Training). Once the contacts are added below, the CITI Human Subject Trainings you have completed, and their expirations will be reflected below. As these trainings are now pulling directly from CITI, you do not need to upload a certificate if they are included below.

CITI Program Home Page

Please list all other co-investigators for this study with complete contact information.

[redacted]

Expirations: Biomedical Research-Basic/Refresher - 02/03/2025 • Social & Behavioral Research-Basic/Refresher - 02/02/2025

If the contact is not found in IRBManager, please complete the form at the bottom of this page. Please note: Co-investigators will have access inside IRBManager to view study documents.

[redacted]

Expirations: Biomedical Research-Basic/Refresher - 09/11/2025

Please list all other study personnel.

No answer provided.

If the contact is not found in IRBManager, please complete the form at the bottom of this page. Please note: Other Personnel will not have access inside IRBManager to view study documents.

Please click the following link if you need to add a user to IRBManager. You will receive an email (usually within a minute or two) after you submit the form informing you that the contact is now available for adding to your submission.

User had the option to start a different form here.

Section C: Study Design, Methods & Procedures

Section C: Study Design, Methods & Procedures

Describe how this research expands the existing scholarly literature.

A warm-up is a widely accepted practice performed by athletes prior to training sessions and competitions. Establishing an effective warm-up plays a critical role in optimizing overall performance (4). A warm-up can benefit performance and prevent injury by increasing core

In this section, provide the reviewer with the scholarly context from which the project emerges. This section should contain enough

body temperature, blood flow, nerve impulse transmission, metabolic activity, and tissue extensibility. Warm-ups can also prime muscles, joints, ligaments, and tendons to increase flexibility and range of motion (2,4,6). While various types of warm-ups can elicit these common benefits, protocols are often developed by trial and error, and not always scientifically tested. There are several variables that can be altered in warm-up protocols such as mode, duration, and intensity. These variables can elicit different effects on performance. Post-activation potentiation (PAP) is based on the proposition of performing a heavy resistance exercise prior to an explosive exercise. PAP is a phenomenon known to cause an acute increase in voluntary muscle activation through this heavy resistance conditioning activity performed at near maximal intensity. PAP induced through resistance training has been shown to increase anaerobic power output and performance during explosive sport activities such as running, jumping, and throwing, when compared to a conventional warm-up routine (5). There are several variables to consider that can influence PAP results. Research has yet to determine the perfect combination of exercise choice, volume, rest time, intensity, and training status to elicit PAP. The magnitude of PAP is dependent upon the fatigue-potentiation relationship. Following a stimulus, fatigue will occur which inhibits potentIation. As one recovers, fatigue is reduced, and the onset of potentiation occurs (6). Because of this fatigue-potentiation relationship, there is a large window for PAP that can be influenced by the mode and intensity of a specific PAP protocol. The NSCA claims that elite athletes may experience positive muscle enhancement between 2 and 20 minutes following a PAP conditioning activity due to an increase in the intensity of phosphorylation of myosin light chain, increased density of higher order motor units, and reduction in pennation angle following a maximal voluntary contraction (1). There is a lack of research studying the optimal rest time for PAP. This is likely due to the other factors that can also influence the window for potentiation. Therefore, the purpose of this study is to determine the ideal rest time is after a bout of post-activation potentiation, via weighted vest jumps, to elicit the highest vertical jump performance.

1. Ah Sue R, Adams KJ, DeBeliso M. (2016) Optimal Timing for Post-Activation Potentiation in

information to provide the reviewer with an understanding of how/why the use of human participants is warranted.

Women Collegiate Volleyball Players. Sports (Basel);4(2):27. doi: 10.3390/sports4020027. PMID: 29910275; PMCID: PMC5968915.
2. Fortier, J., Lattier, G., & Babault, N. (2013). Acute effects of short-duration isolated static stretching or combined with dynamic exercises on strength, jump and Sprint Performance. Science & Sports, 28(5). https://doi.org/10.1016/j.scispo.2012.11.003
3. Sevene T. G., DeBeliso M., Carson C., Berning J. M., Harris C., Adams K. J. (2017). Continuous weighted jumping: Effects on vertical jump height. Zenodo. Retrieved April 26, 2023, from https://zenodo.org/record/847756#.ZElbOnbMK3A
4. Schleper, A., Rempel, M. E., Scribbans, T., Anzalone, R., & Villar, R. (2022). Effects of dynamic warm-up on anaerobic performance: A randomized, counterbalanced, and cross-over study. Research in Sports Science, 11(2), 39–46. https://doi.org/10.5152/rss.2021.21007
5. Tillin, N. A., & Bishop, D. (2009). Factors modulating post-activation potentiation and its effect on performance of subsequent explosive activities. Sports Medicine, 39(2), 147-166.
6. Gasch, L., Olmedo, J., Amat, S., Pueo, B. (2020). Squat- based post-activation potentiation improves the vertical jump of elite female volleyball players. Journal of Physical Education and Sport, 2020(04). https://doi.org/10.7752/jpes.2020.04264

Provide a brief timeline for major activities in your study.

Subjects will be recruited by word of mouth and with flyers hanging in [redacted] building after IRB approval is received. Data collection will begin when the fall semester starts (8/21/23) with an anticipated end date of before the semester ends (12/8/23). Data analysis will occur after data collection is complete and a poster will be submitted for presentation in the fall of 2024.

Please choose all the appropriate project attributes that apply to your study.

Biomedical
Blood Samples
Exercise Equipment
Observation
Participant Observation
Physical Assessment
Written Survey

Please describe the quantitative, qualitative, and/or mixed methods proposed for the study in detail.

Subjects will begin to be recruited by word of mouth and with flyers hanging in Willis Health Professions Building after IRB approval is received. Each subject will complete i a Physical Activity Readiness Questionnaire (PARQ) and exercise history questionnaire to indicate prior participation in physical activity to ensure qualification for the study. Subjects will be screened to ensure they meet current ACSM physical activity guidelines (at least 30 min moderate intensity 5d a week, or 20 min vigorous activity 3d a week). Subjects are required to have at least 6 months of resistance training experience and a self-reported 1 RM max back squat of 1.5kg per 1kg body weight for males and 1.0kg per 1.0kg body weight for females for inclusion into the study.

Each subject will attend 5 sessions, the first lasting approximately 30 minutes, and the following 4 sessions will last anywhere from 15 to 35 minutes, depending on the rest time condition for that day, and the length of time the subject jumps for. Their total time commitment for this study will be approximately 130 minutes or less, spread across 5 visits, depending on the number of jumps taken. The visits will be scheduled 3-14 days apart.

During the first visit, informed consent forms and an explanation of the study will be conducted. Next, demographic data will be collected. First, standing height (to the nearest 0.1 cm) will be measured without shoes with a stadiometer (Detecto, Webb City, MO). Then, body mass will be measured (to the nearest 0.1 kg) without shoes while body composition is assessed with a bioelectric impedance analyzer (BIA: BioSpace InBody 520, Seoul, Korea). Next, the subjects will complete a 5-minute dynamic warm-up that consists of several full body movements. The dynamic warm-up consists of (in specific order) 20 high knees, 20 buttock kickers, 20 lunges, 20 karaoke, 20 side shuffles, 20 walking quad/ hamstring stretch, 10 leg swings, 10 medium arm circles, and 20 large arm circles. Following the dynamic warm-up, the subjects will have 2 minutes of rest. They then will be asked to complete a maximal vertical jump test on a jump mat which assesses jump height via time in the air. Following the maximal vertical jump test, the subjects will perform a Post Activation Potentiation (PAP) familiarization trial. The subjects will perform 30 seconds of continuous counter movement vertical jumps, wearing a vest that is loaded with 30 percent of their measured bodyweight (rounded to the nearest 8.0 lb due to constraints of the vest). They will be asked to jump as high as possible, as many times as possible, in thirty seconds. The number of repetitions completed in this 30 second familiarization trial will be recorded as a baseline for the following four trials. Ratings of perceived exertion, both overall (RPE-O) and peripheral (RPE-P) will be assessed using the Borg 6-20 Scale, to indicate the difficulty of the exercise being performed. Subjects will then be given the opportunity to ask any questions they may have before being scheduled for their data collection session. Participants will then be told when they will be expected for data collection (3-14 days after the first visit).

During the next four visits, the subjects will be exposed to four different rest time conditions. Upon arrival to the lab, subjects will be pricked on the finger for assessment of blood lactate (Lactate Plus Meter, Nova Biomedical, Walthan, MA), a marker of exercise intensity. They will then complete the same dynamic warmup as visit 1, have two minutes of rest and then complete their PAP

protocol again, being asked to complete the same number of jumps as recorded in their familiarization trial. After the PAP protocol, they will then be pricked on the finger again to assess blood lactate, and local and peripheral ratings of perceived exertion will be assessed. Following completion of the PAP protocol, after their designated rest time for that condition, the subject will be asked to perform a maximal vertical jump on the jump mat once every minute, for ten minutes, or until they have two consecutive decreases in jump height. RPE-P and RPE-O will be assessed after every jump. Blood lactate will be assessed after their final jump. Subjects will have a self-selected cooldown as desired.

The four different rest time conditions will alter the amount of time that has passed from the completion of the PAP protocol to the beginning of their vertical jump testing; these times will be 4 minutes post-PAP, 8 minutes post-PAP, 12 minutes post-PAP and 16 minutes post-PAP in a counterbalanced order.

Please describe data analysis procedures.

Descriptive statistics will be calculated for demographic data, jump heights, Blood Lactate, Heart Rate, and Rate of Perceived Exertion (RPE). Repeated measures ANOVAs will be used to compare the jump height, RPE, blood lactates, and heart rate across the 4 resting conditions (4,8,12,16 mins).

Section D: Target Sample Demographics

Section D: Target Sample Demographics

Anticipated number of total subjects involved in this study.

16

What is age range for participants in this study?

18-30

Enter the specific age range of minimum and maximum ages. Or indicate adults who are 18 or older.

Please list all inclusion criteria for participants.

Healthy (according to the Physical Activity Readiness Questionnaire+ (PARQ+)) and recreationally active (defined by meeting current ACSM physical activity guidelines (at least 30min moderate- intensity 5d a week or 20min vigorous activity 3d a week)) male and female subjects ranging from 18-30 years who have at least 6 months of prior resistance training. Subjects are required to have a self-

Inclusion criteria are characteristics that the perspective subjects must have if they are to be included in the study. (i.e. Age, Sex, Race, Ethnicity, Medical conditions)

reported 1 RM max back squat of 1.5kg per 1kg body weight for males and 1.0kg per 1.0kg body weight for females.

Please list all exclusion criteria for participants

As determined by the PARQ+, individuals with orthopedic, cardiovascular, and/or metabolic contraindications to aerobic exercise will be excluded from participating in this study. In addition, those who do not meet the current ACSM physical activity guidelines (at least 30min moderate- intensity 5d a week or 20min vigorous activity 3d a week) or do not have at least months of resistance training. Individuals that do not have a self-reported 1 RM max back squat of 1.5kg per 1kg body weight for males and 1.0kg per 1.0kg body weight for females are also excluded from this study.

Exclusion criteria are those characteristics that disqualify perspective subjects from inclusion in the study.

Vulnerable populations: Please select any/all attributes that apply to your proposed sample.

No answer provided.

If you intend to study a population that at are vulnerable to coercion or undue influence, such as children, incarcerated persons, individuals with impaired decision-making abilities, or economically or educationally disadvantaged persons, justify the importance of their use. Here and throughout the protocol discuss how their vulnerability will be matched with appropriate safeguards.

Section E: Recruitment of Participants

Section E: Recruitment of Participants

Describe how subjects will be identified and recruited, including who will perform the recruitment.

Recreationally active individuals will be recruited by word of mouth, and with flyers hanging in [redacted] building after IRB approval is

received. The student investigator will recruit in Health Science classes as necessary (see attached verbal script and flyer)

Will participants be provided some form of incentive or compensation?

Yes

This could include cash payment, extra credit, gift cards, etc.
Compensation should not unduly influence potential participants, and must be approved by the IRB.

Describe the Participant Compensation you will use, i.e. gift cards, payments, other incentives, etc.

Participants will receive a report on their body composition, which is typically an $85 fee in most laboratories, after their first visit.

Section F: Benefits & Risks

Section F: Benefits & Risks

Federal regulations, based on the ethical principle of beneficence, require that risks of harm associated with research are reasonable in relation to the potential benefits (Protection of Human Subjects 2018).

Describe the possible direct benefits to the subjects. If there are no direct benefits, please state this fact.

There is no guarantee that the participant will get any benefit from taking part in this study. The participant's willingness to take part, however, may, in the future, help practitioners better understand this body of knowledge.

Describe the possible benefits to society.

Possible benefits to society include a further increase in knowledge and application of optimal rest time following post activation potentiation on vertical jump performance. This study may assist other researchers and practitioners in the future by building a larger foundation of knowledge of optimal rest time following post activation potentiation on vertical jump performance.

Please describe any foreseeable risks to participants. Consider physical, psychological, social, legal, economic and other potential risks.

The risks imposed by participating in physical exercise are minimal. It is expected that the subjects will experience some degree of generalized muscular fatigue as a

Please note that risks, although they may be minimal, are always present. If risks are no more than one would experience in daily life, please state so.

result of the exercise sessions. As with any moderate to high-intensity activity, muscle fatigue, joint pain, cramps, dizziness, cardiorespiratory distress, and even death are all possible situations that could arise.

Studies have reported that the absolute risk of sudden cardiac death during vigorous physical activity is one death per year for every 15,000-18,000 people. However, in light of these aforementioned risks, we will minimize these risks by following American College of Sports Medicine Guidelines for testing protocols, closely monitoring the performance of the testing protocols, and use of qualified technicians. Dr. Lesniak is a certified exercise physiologist through the American College of Sports Medicine and is experienced in exercise testing.

Finger stick for blood lactate can cause pain, soreness, bruising, bleeding, infection, or fainting. This occasionally occurs, but will not have an impact on your overall health.

Describe the procedures for protecting against or minimizing potential risks and provide an assessment of their likely effectiveness.

Consider mechanisms to protect against or minimize potential risks; i.e. if you will be conducting an interview that may cause potential psychological risks, will there be counseling available, or external resources provided to contact, etc.

In order to protect participants from risk, [redacted] the principal investigator will supervise all testing sessions. She is CPR/AED/First Aid instructor trained. Although highly unlikely, if an adverse event occurs [redacted] will have a cell phone available to call 911 and [redacted] Law Enforcement (2522) for assistance. [redacted] Law Enforcement will provide access to an external defibrillator if needed. All research assistants [redacted] will be trained by qualified personnel to conduct each physical fitness assessment safely. In case of an emergency, the research assistant will be present and is trained in CPR and first aid. All of the subjects will be assisted and instructed by trained study personnel during all of

the testing sessions to reduce the likelihood of injury. Subjects will be supervised 100% of the time during this research study. All participants will be assigned a study code number and will only be identified by that number after the testing session to ensure subject confidentiality. The only individuals who will have access to that information will be [redacted]. For the finger stick-Lactate, the area will be kept clean and covered with a band-aid to reduce risk and ensure quick healing.

Please evaluate the probability and magnitude of the possible harms, when compared to the probability and value of the possible direct benefit to the subject.

The probability of injury or risk is always possible. However, in light of these aforementioned risks, we will minimize these risks by following American College of Sports Medicine Guidelines for testing protocols, closely monitoring the performance of the testing protocols, and use of qualified technicians. The likelihood as to which these risks may cause any actual harm is small, and there are protocols in place to handle them safely and effectively in case anything unexpected were to happen. In addition, all subjects being recruited are recreationally active with resistance training experience and would be partaking in this behavior if they were not in the study. In terms of value and possible direct benefit, there is no promise that participants will directly benefit from the study; in other words, the risk to benefit ratio is about equal.

Section G: Informed Consent

Section G: Informed Consent

Obtaining informed consent from research participants is a basic ethical obligation and a legal requirement for researchers. This requirement is founded on the principle of respect for persons, one of the 3 ethical principles governing human subject research described in the Belmont Report. The principle of respect for persons requires that individuals be treated as autonomous agents and that the rights and welfare of persons with diminished autonomy be appropriately protected. *How that consent is obtained and documented varies based on the research design and the level of risk.*

Resources: Informed Consent FAQ Informed Consent FAQ
Informed Consent Checklist Informed Consent Checklist

Please be sure to include the IRB number (once assigned to the study), Commonwealth University of PA, and CUP-IRB Chair name and contact information. The CUP-IRB Chair contact information can be found here CUP-IRB website .

Please describe the informed consent process in detail. The informed consent process includes: 1) Providing information to the subject, 2) Answering questions to improve the subjects comprehension, and 3) Obtaining the subjects' voluntary agreement to participate in the study.

During the first visit, the subject will be verbally explained the purpose of the study and the entire methodology while they are in the exercise physiology lab in the Willis Health Professions Building. After answering any questions, the subjects will be given the informed consent form to read and then given the opportunity to ask more questions. If the subject agrees to participate in the research study, it will be reiterated that they are free to withdraw at any point in time. After signing the informed consent, they will receive a copy of their own to keep.

Do not answer, "see attached consent form," as this does not describe the process of obtaining informed consent. Describe how, when and where the informed consent process will take place and who will obtain informed consent. You will attach a copy of the consent form at the end of the application.

If the participants are not able to give legal consent, (i.e. minors) explain how assent will be secured.

No answer provided.

Are you requesting an alteration or waiver to any informed consent requirements, including documentation of informed consent (signed consent)?

No

Section H: Protection from Coercion

Section H: Protection from Coercion

Is there an unequal power relationship that may influence participant's decision to participate in this research?

No

If you are a professor, will you be recruiting participants from your class?

No

Please describe any other possible form of coercion.

N/A

Section I: Privacy & Confidentiality

Section I: Privacy & Confidentiality

The Common Rule (45 CFR 46, Subpart A) states that when reviewing research proposals, Institutional Review Boards (IRBs) must determine that there are adequate provisions for protecting the privacy of subjects and maintaining the confidentiality of data.There may be other federal laws that further restrict how you must maintain confidentiality/privacy. For example, the Family Educational Rights and Privacy Act (FERPA) protects the disclosure of educational records, while the Health Insurance Portability and Accountability Act (HIPAA) protects against the dissemination of private health information.

Privacy is defined as having control over extent, timing and circumstance of sharing oneself (physically, behaviorally, or intellectually) with others. Threats to privacy are mitigated by the participant's informed consent of participation in the research.

Describe the provisions to protect the privacy of the participants during the data collection procedures.

All participants will be assigned a study code number and will only be identified by that number after the first testing session to ensure subject confidentiality. [redacted] will be the only individuals with access to this information, any other researchers or observers will not have access to that recorded data.

If your research requires medical records, have you included the Authorization for Use of Private Health Information with your application.

No answer provided.

Confidentiality refers to how DATA is handled, stored, and shared after collection. It is the treatment of information already revealed and states that there is an expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission (i.e. data is stored on a password protected computer, locked filing cabinet, data is coded or de-identified, and only researchers have access to data).

Provide details as to how you plan to protect the data while on site and during travel (i.e. from data collection site back to campus). When

traveling, data security is vital, especially if the data or storage device is lost or stolen. Address the storage and security of electronic data as well as any physical data, such as paper consent forms/surveys.

Data will be kept in physical copies on paper. On these papers, only subject codes will be used, names of participants will not be on the same paper as assigned subject codes. The physical copy will be kept in a plain, unmarked folder, and will remain in the possession of either [redacted] (or in the office of [redacted]) between data collection sessions and data analysis sessions. When transferred to electronic data sheets, data will be recorded using subject codes only. Only [redacted] will have access to both the physical copy of the document and the online copy of the document. Physical copies of consent forms and surveys taken during data collection will be kept in a separate folder labelled as such.

Describe how you will maintain confidentiality of the data after it has been collected, including measures to protect the identity of the participants and their responses.

i.e. Coding procedures, encryption, etc.

All participants will be assigned a study code number and will only be identified by that number after the first testing session to ensure subject confidentiality. [redacted] will be the only individuals with access to this information, any other researchers or observers will not have access to that recorded data. In any writing or data analysis, subjects will only be referred to by their assigned code. On any document filled out by the subject, their code will be used, and not any other identifying features.

Please explain how data will be shared and who will have access to the data.

Data will be shared only between [redacted] Data will be collected and stored on paper or electronic files, with no one else possessing the link to be able to access said documents. Email correspondence may occur between [redacted], and may include documents with data from the study as attachments; however, as stated prior, subjects will only ever be referred to by their code, even in email correspondence.

Section J: International Research

Section J: International Research

This section is only to be completed if your potential subjects reside outside of the United States.

Resources
- ClinRegs.gov offers free access to country-specific information on a wide range of clinical research regulations and requirements, including ethical review, informed consent, vulnerable populations, and a variety of other topics
- U.S. Department of Health and Human Services (HHS) Office for the Protection of Human Subjects (OHRP). 2020. "International Compilation of Human Research Standards."
- U.S. Department of Health and Human Services (HHS) Office for the Protection of Human Subjects (OHRP). 2018. "Listing of Social-Behavioral Research Standards."

Does the proposed study involve international participants?

No

Section K: All Study Attachments

Section K: All Study Materials

CITI Human Subject Training- the IRB Manager system now tracks CITI Training for Commonwealth University. Only use this space to upload any CITI's obtained outside the University subscription.

CITI training.pdf	Human Subj Trng Doc	*Please ensure all study personnel complete either the Human Subject Research "Biomedical" or "Social & Behavioral" CITI training courses. Certificates of completion are good for a period of three (3) years where then the person will need to complete a refresher course. Double check your expiration date prior to uploading.*

Please attach a copy of Certifications or Licenses that you as the PI possess as they relate to the procedures of this study methodology.

No answer provided.		*As Applicable.*

Recruitment Materials

Study Flyer [redacted].docx	Questionnaire	*Please be sure to attach all recruitment materials, including any advertisements, flyers, emails and letters. Please be sure all recruitment materials include the IRB number, Commonwealth University of PA, and CUP-IRB Chair name and contact information. The CUP-IRB Chair contact information can be found here CUP-IRB website .*
Verbal Script [redacted].docx	Questionnaire	

Survey instruments, questionnaires, tests, debriefing information,

interview script etc.

Exercise History Questionnaire Isaiah Reed.docx	Questionnaire	*Please attach a copy of all survey instruments, questionnaires, tests, debriefing information, interview script etc. that will be used in this research.*
PARQ+.pdf	Questionnaire	
RPE scales.docx	Questionnaire	

Informed consent and as applicable, the parental permission and assent forms.

[redacted] Consent Form.docx	Consent Form	*Attach the informed consent form as well as any parental permission and assent forms as applicable. Please be sure to include the IRB number (once assigned to the study), Commonwealth University of PA, and CUP-IRB Chair name and contact information. The CUP-IRB Chair contact information can be found here CUP-IRB website. An informed consent template is available for your use. Also see details below for required elements of an informed consent.* *According to 46.116(b), legally appropriate informed consent will include the following elements:* *1. A statement that the study involves research, an explanation of the research's purposes and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.* *2. A description of any reasonably foreseeable risks or discomforts to the subject.* *3. A description of any benefits to the subject or to others that may reasonably be expected from the research.* *4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.* *5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (and for FDA-regulated research it should note the possibility that the FDA may inspect the records).* *6. For research involving more than minimal risk, an explanation as to whether any*

compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

7. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject.

8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used

Additional Requirements

In addition, if relevant to the research, legally effective informed consent will also include the following elements, outlined in 45 CFR 46.116(c):

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.

2. Anticipated circumstances under which the subject's participation may be terminated by the researcher without

regard to the subject's or legally authorized representative's consent.

3. Any additional costs to the subject that may result from participation in the research.

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

6. The approximate number of subjects involved in the study.

7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (that is, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). or distributed for future research studies.

Please attach a copy of your written approval to access any Health Information Data.

No answer provided.

For example, a letter may be needed if you are proposing to utilize data from the Speech, Hearing, and Language clinic on campus, or if you are using data from Geisinger.

Please attach a copy of your Certificate of Confidentiality if it applies by Federal Regulation to this study.

No answer provided.

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) (an agency of the U.S. Department of Health and Human Services [HHS]) to protect sensitive, identifiable research information from forced disclosure. The certificates may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.

External IRB Approval.

No answer provided.

Please attach a copy of the approval letter if this research was approved by an external IRB. For example, another University or Geisinger.

You may use this attachment to upload a student project proposal/s, if applicable.

No answer provided.

PI or Student Signature

By entering my password below I am attesting that all of the above information is true and accurate to the best of my knowledge. I certify that the application has been reviewed for clarity, validity, and the protection of human subjects. Please note, that if you are not the PI, the application will route to the PI for review and final signature prior to moving forward to the BU-IRB for review.

Submitters signature.

Signed Thursday, April 27, 2023 10:34:19 AM ET by [redacted]

Please enter your password to electronically sign this document.