**DATA and/or SPECIMEN ONLY PROTOCOL**

**GENERAL INSTRUCTIONS:**

**Data Review Guidance:**

***What is the difference between a retrospective and prospective review?***

* A Retrospective Review evaluates participant data that exists at the time the study is submitted to the IRB for initial review.
* A Prospective Review evaluates participant data that does not yet exist at the time the project is submitted to the IRB for initial review.

***What type of consent should I request?***

* *Waiver of Consent:* Waiver of consent is often appropriate for both retrospective and prospective reviews. In order for the IRB to approve a waiver of consent, the IRB must be satisfied that the following criteria in “[CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)](https://research.umn.edu/units/irb/toolkit-library/checklists)” are met:
* The research involves no more than minimal risk to the participants;
* The waiver or alteration will not adversely affect the rights and welfare of the participants;
* The research could not practicably be carried out without the waiver or alteration; and
* Whenever appropriate, the participants will be provided with additional pertinent information after participation.
* If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

*Waiver of Documentation of Consent:* This type of consent is not usually requested for a data review. Under a waiver of documentation of consent, an investigator must still obtain consent from the participant. However, the investigator does not need to obtain a signed consent form from participants if the IRB agrees that the criteria in “[CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)](https://research.umn.edu/units/irb/toolkit-library/checklists)” are met:

* The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether she or he wants documentation linking her or him with the research, and the participant's wishes will govern; or
* The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.
* *Written Consent:* The IRB may determine that written consent is required if the investigator is unable to justify why it is impracticable to conduct the research without a waiver. This is often the case for prospective review studies, but may occur in retrospective review studies. For example, if an investigator wishes to review the data of all of the patients he refers onward for a colonoscopy to collect outcome measures, the IRB may determine that the investigator should obtain written consent because he will have the chance to obtain consent from the patients during their clinic visit with him.

**ANCILLARY REVIEWS**

**DO NOT DELETE. Submit the completed checklist below with your protocol.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Which ancillary reviews do I need and when do I need them?**  Refer to [HRP-309](https://drive.google.com/file/d/0B7644h9N2vLcMTl0ZE9yQkhLd3c/view) for more information about these ancillary reviews. | | | |
| **Select yes or no** | **Does your study…** | *If yes…* |  |
| **Yes**  **No** | Include Gillette resources, staff or locations | *Gillette Scientific review and Gillette Research Administration approval is required. Contact:*  [*research@gillettechildrens.com*](mailto:research@gillettechildrens.com) | **Required prior to IRB submission** |
| **Yes**  **No** | Involve Epic, or Fairview patients, staff, locations, or resources | *The Fairview ancillary review will be assigned to your study by IRB staff*  *Contact:* [ancillaryreview@Fairview.org](mailto:ancillaryreview@Fairview.org) | **Approval must be received prior to IRB committee/ designated review.**  **Consider seeking approval prior to IRB submission.** |
| **Yes**  **No** | Include evaluation of drugs, devices, biologics, tobacco, or dietary supplements or data subject to FDA inspection | *The regulatory ancillary review will be assigned to your study by IRB staff*  *Contact:* [*medreg@umn.edu*](mailto:medreg@umn.edu) |
| **Yes**  **No** | Require Scientific Review? Not sure? See guidance in the [Investigator Manual (HRP-103)](https://drive.google.com/uc?export=download&id=0B7644h9N2vLcOWtzU2FmSU5oS0U). | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) |
| **Yes**  **No** | Relate to cancer patients, cancer treatments, cancer screening/prevention, or tobacco  NOTE: CPRC review is not required for Retrospective Chart Review, Retrospective Sample Review, or Prospective Specimen Repository studies | *Complete the* [*CPRC application process*](https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee)*.*  *Contact:* [*ccprc@umn.edu*](mailto:ccprc@umn.edu) |
| **Yes**  **No** | Include the use of radiation  (x-ray imaging, radiopharmaceuticals, external beam or brachytherapy) | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) | **Approval from these committees must be received prior to IRB approval;**  **These groups each have their own application process.** |
| **Yes**  **No** | Use the Center for Magnetic Resonance Research (CMRR) as a study location | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) |
| **Yes**  **No** | Include the use of recombinant or synthetic nucleic acids, toxins, or infectious agents | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) |
| **Yes**  **No** | Include the use of human fetal tissue, human embryos, or embryonic stem cells | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) |
| **Yes**  **No** | Use data from [CTSI Best Practices Integrated Informatics Core](https://ctsi.umn.edu/services/data-informatics/biomedical-informatics-and-data-access)  (Formerly the Information Exchange) | *See instruction within this template.*  *Contact:*  [bpic@umn.edu](mailto:bpic@umn.edu) | **Approval must be received prior to IRB approval.**  **These groups do not have a separate application process but additional information from the study team may be required.** |
| **Yes**  **No** | Include PHI or are you requesting a HIPAA waiver | *If yes, HIPCO may conduct a review of this protocol.*  *Contact:* [*privacy@umn.edu*](mailto:privacy@umn.edu) |
| **Yes**  **No** | Use the Biorepository and Laboratory Services to collect tissue for research | *The BLS ancillary review will be assigned to your study by IRB staff.*  *Contact: Jenny Pham*  *Pham0435@umn.edu* |
| **Yes**  **No** | Have a PI or study team member with a conflict of interest | *The CoI ancillary review will be assigned to your study by IRB staff*  *Contact:* [*becca002@umn.edu*](mailto:becca002@umn.edu) |
| **Yes**  **No** | Need to be registered on clinicaltrials.gov | *If you select “No” in ETHOS, the clinicaltrials.gov ancillary review will be assigned to your study by IRB staff*  *Contact:* [*kmmccorm@umn.edu*](mailto:kmmccorm@umn.edu) |
| **Yes**  **No** | Require registration in OnCore | *If you select “No” or “I Don’t Know” in ETHOS, the OnCore ancillary review will be assigned to your study by IRB staff*  *Contact:* [*oncore@umn.edu*](mailto:oncore@umn.edu) | **Does not affect IRB approval.** |

**PROTOCOL COVER PAGE**

|  |  |
| --- | --- |
| **Protocol Title** | Gas Exchange Data Processing |
| **Principal Investigator/Faculty Advisor** | Name: Christopher Lundstrom |
| Department: Kinesiology |
| Telephone Number: |
| Email Address: lund0982@umn.edu |
| **Student Investigator** | Name: Anton Hesse |
| Current Academic Status (Student, Fellow, Resident): Student |
| Department: Kinesiology |
| Telephone Number: (612) 616-0944 |
| Institutional Email Address: hesse151@umn.edu |
| **Biospecimens and/or Data** | Medical record number  Patient ID (generated by CTSI)  Gas exchange data files from exercise tests  Age at each test  Test date / test ID  Sex |
| **Number of Records and/or Specimens** | N# of Records: Approximately 250 patients,  N# of Specimens: Most patients will have between 1-3 exercise test files. We estimate there will be approximately 350 exercise test files. |
| **Version Number/Date:** | 2  5/20/2022 |

**REVISION HISTORY**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
| 1 | 5/20/2022 | Anton has now completed the CITI training Good Clinical Practice and Human Research Protections for Biomedical Study Teams - Basic Course | No changes to consent process |
|  |  |  |  |
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NOTE: Leave this section blank for the initial submission. The revision history should be documented for modifications to approved studies.

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**ABBREVIATIONS/DEFINITIONS**

* VT1 and VT2: the first and second ventilatory threshold, respectively
* LOA: limits of agreement
* VO2 and VO2max: volume of oxygen and maximal aerobic power or maximal oxygen consumption, respectively
* HRmax: maximal heart rate
* MRN: medical record number

# **Objectives**

* 1. Purpose:

The purpose of this study is to quantify the effects of different data processing methods on algorithm-selected values for VT1 and VT2.

Aim 1: Calculate the LOA for the absolute VO2, %VO2max, and time at VT1 and VT2 while modifying combinations of prior data processing and analysis steps including outlier selection, interpolation, data averaging, threshold graph, and threshold algorithm choice.

We hypothesize that some combinations of data processing and analysis steps will result in LOA that are wider than the expected error in the measurement device.

# **Background**

* 1. Significance of Research Question/Purpose:

Exercise intensity is likely the most challenging exercise prescription variable to individualize. Without information from an exercise test, the next best alternative to prescribe cardiovascular exercise is to use percentages of maximal anchors or percentages of reserve anchors, such as %HRmax or % heart rate reserve, respectively. These methods typically incorporate different zones such as 50-59%, 60-69%, 70-79%, etc. of %HRmax. Unfortunately, what may be a moderate or challenging zone or a given %HRmax for one individual may be easy for another. Previous research shows that prescribing cardiovascular exercise from physiological thresholds, such as VT1 and VT2, typically yields better and more predictable improvements to fitness. If one can determine these thresholds, they must be calculated correctly for accurate exercise prescription.

One source of data used to find these thresholds is ventilatory data from an exercise test. The gases released at the mouth reflect whole-body metabolism and therefore exercise intensity, but there is considerable variability breath to breath. Most of this variability originates from rapidly oscillating ventilation, rather than slower metabolism. Therefore, some data processing, such as removing outliers, interpolating data, and averaging the data, is required to uncover the underlying metabolic demand.

Our lab recently analyzed pilot data where we averaged ventilatory in five different ways and then used a common algorithm to locate VT1. The results of our pilot data show that on average, the VO2, %VO2max, and time at VT1 are similar between averaging methods. However, calculating the LOA between any two method shows this LOA is var wider than the error expected in the measurement. This suggests that the choice of averaging method likely plays a practically significant role in the ultimate exercise prescription from the values at VT1.

Therefore, the purpose of this study is to extend our analysis to a larger data set and incorporate more data analysis choices including outlier boundaries, data interpolation, and other steps that may influence the final values at VT1 and VT2. We will quantify the effect of these choices by calculating the LOA between different data processing and analysis sequences.

* 1. Preliminary Data:

We have pilot data from the marathon training class at the University of Minnesota (PE 1262). At the beginning of the semester, they underwent pre-testing, including a VO2max treadmill test. With this data we quantified the LOA for the VO2, %VO2max, and time at VT1 between different averaging methods. The results indicate that the LOAs for all comparisons are wider than the expected error in the device measurement.

* 1. Existing Literature:

Previous research on exercise intensity finds that using submaximal thresholds such as VT1 and VT2 to individualize prescription produce superior changes to fitness compared to using standardized methods such as %HRR (Weatherwax et al., 2019; Wolpern et al., 2015). Specifically, these studies find that using these thresholds results in 100% of participants improving their VO2max, while only about half of participants using standardized methods improved VO2max. VO2max does not capture all aspects of cardiovascular fitness, but every 3.5 point increase in relative VO2max translates to a 13 and a 15% decrease in annual all-cause and coronary heart or cardiovascular disease event mortality, respectively (Kodama, 2009). Therefore, this prognostic value and the benefits of using submaximal thresholds to improve VO2max supports the value in reliably detecting and using thresholds to prescribe exercise when possible.

Using ventilatory data is a non-invasive and common method to determine these thresholds. Collecting exhaled gases at the mouth reflects whole-body metabolism, but oxygen consumption from breath to breath is highly variable and differs by up to 86% (Robergs et al., 2010). Whole-body metabolism changes much more slowly, so some data processing is required to parse the signal from the noise. To date, there are no universally agreed upon data processing steps and research on this topic is limited the effect of different averaging methods on the attainment and value of VO2max. (Astorino, 2009; Astorino et al., 2000; Robergs et al., 2010).

This research will extend previous analyses by considering not only the averaging method, but also the effects of different outlier thresholds, data interpolation, and combinations of those choices on the values at VT1 and VT2. Previous research estimates the measurement error in VO2 to be approximately 0.091 L/min (Robergs & Burnejtt, 2003). The average LOA (Altman & Bland, 1983) between averaging methods at VT1 from out pilot study are about 0.31 L/min, or about 3.5 as wide as the expected error. This suggests that data processing choices meaningfully contribute to the intensity at submaximal thresholds and the resultant exercise prescription.

**References**

Altman, D. G., & Bland, J. M. (1983). Measurement in Medicine: The Analysis of Method Comparison Studies. *The Statistician*, *32*(3), 307. https://doi.org/10.2307/2987937

Astorino, T. A. (2009). Alterations in VO2 max and the VO2 plateau with manipulation of sampling interval. *Clinical Physiology and Functional Imaging*, *29*(1), 60–67. https://doi.org/10.1111/j.1475-097X.2008.00835.x

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Robergs, R. A., & Burnejtt, A. F. (2003). METHODS USED TO PROCESS DATA FROM INDIRECT CALORIMETRY AND THEIR APPLICATION TO VO2MAX. *Journal of Exercise Physiology Online*, *6*(2), 44–57. https://www.asep.org/asep/asep/Robergs3.pdf

Robergs, R. A., Dwyer, D., & Astorino, T. (2010). Recommendations for improved data processing from expired gas analysis indirect calorimetry. *Sports Medicine*, *40*(2), 95–111. https://doi.org/10.2165/11319670-000000000-00000

Weatherwax, R. M., Harris, N. K., Kilding, A. E., & Dalleck, L. C. (2019). Incidence of VO2max Responders to Personalized versus Standardized Exercise Prescription. *Medicine and Science in Sports and Exercise*, *51*(4), 681–691. https://doi.org/10.1249/MSS.0000000000001842

Wolpern, A. E., Burgos, D. J., Janot, J. M., & Dalleck, L. C. (2015). Is a threshold-based model a superior method to the relative percent concept for establishing individual exercise intensity? a randomized controlled trial. *BMC Sports Science, Medicine and Rehabilitation*, *7*(1), 1–9. https://doi.org/10.1186/s13102-015-0011-z

# **Procedures Involved**

* 1. Study Type (check all that apply):

Retrospective Review

Prospective Review

Both: Retrospective and Prospective Review

* 1. Identify the Source of the individually identifiable information (Check all that apply)

Information Exchange (IE) Services through CTSI Best Practices Informatics Consulting (BPIC)

* Include a copy of the [BPIC](https://www.ctsi.umn.edu/consultations-and-services/data-access-and-informatics-consulting/bpic) Consultation form with the IRB Submission
* Limited access to [EPIC](https://www.epic.com/) through the AHC-IE Security Gateway for validation/supplemental purposes only.

EPIC records accessed outside of the Information Exchange. Please provide the information requested below:

Information will be collected directly from research participants

I will retrieve records directly from axiUm / MiPACS

I will receive data from the Center for Medicare/Medicaid Services

I will receive a limited data set from another institution

Other sources of individually identifiable information:

If this project requires only **RETROSPECTIVE REVIEW** and **ALL DATA** will be made available to you by CTSI Best Practices Integrated Informatics Core through the information Exchange you do not need to complete the remainder of this protocol (3.3 – 10, Appendices).

* Upload a copy of your BPIC consultation form with this protocol in ETHOS if you are using the abbreviated process.
* HIPCO and Fairview ancillary reviews are waived for these projects
  1. Date Range: The beginning date is the start of the Executive Health Program at the University of Minnesota Physicians Clinics and Surgery Center. The end date is the day before the IRB submission in Ethos.

* 1. Approximate number of records required for review:

~600

* 1. Research conducted with populations with additional protections:

We are unaware if any records will be associated with populations that require additional protections. The typical age range of patients in the Executive Health program is at least 40 years old, but it is possible that a small number of the women in the program were pregnant at some point.

* 1. Informed Consent:

Upon enrollment in the executive health program or shortly thereafter, patients were asked if they consented to allow their data to be used for research purposes. The information from the CTSI will only return those patients who opted to allow their data to be used for research purposes.

* 1. Study Design:

This is a retrospective study. We will download unaveraged gas exchange exercise test files and use different data processing and analysis methods to determine the VO2 and related measure at submaximal thresholds VT1 and VT­2

* 1. Study Procedures:

This project will focus on collecting relevant data from EPIC by utilizing the AHC Information Exchange (AHC-IE). The Best Practices Integrated Informatics Consulting core (BPIC) will create, store, and maintain the data in their secure data environment.

After obtaining a list of the MRNs from the CTSI, Anton Hesse will access the unaveraged gas exchange exercise test files from the metabolic cart computer in the 5th-floor fitness room in the Clinics and Surgery Center. Anton is a casual employee for the Executive Health program at the Clinics and Surgery Center and usually performs several exercises tests per week. Anton will view the MRNs for those patients found by the CTSI from within the secure server. Using those MRNs, Anton will look up the exercise tests within the Breeze software application. Breeze is the software connected to the metabolic cart hardware that collects the gas exchange measurements.

For each VO2max test a patient has, Anton will open their test, change the data averaging method to unaveraged, and copy and paste their data into a csv or text file. In previous email communications between Anton and MedGraphics, the company that makes Breeze, Anton learned that the only method to obtain the unaveraged data is to manually copy and paste the data. Summary versions of the data are available for automated export, but the basis of this study requires the unaveraged data.

Each exercise test file will be saved and named by combing the patient ID provided by the CTSI with a number indicating the VO2max test year or number. For example, the first VO2max test for patient 03743 could be named 03743\_2019\_cpet.csv. We propose combining the patient ID with a number indicating the test year because several patients complete a VO2max test every 1-2 years. Later statistical analysis will likely require knowing which exercise tests pertain to the same participant when performing a repeated measures ANOVA or similar technique. It is important to note that this file itself does not contain any protected health information.

In addition to downloading the unaveraged exercise test files, Anton will use the secure server to create a spreadsheet containing de-identified patient information including patient ID, VO2max test year, patient sex, and patient age at test. The MRNs and full test dates will *not* be downloaded as they will only be used to obtain exercise test files.

A folder containing the unaveraged exercise test files and the spreadsheet of de-identified patient information will be downloaded to a zip drive for Anton to analyze later on his personal computer.

* 1. Individually Identifiable Health Information:

This study will use individually identifiable health information for the purpose of obtaining the de-identified exercise test files.

# **Health Information and Privacy Compliance**

Under the HIPAA Privacy Rule, research studies at the University are permitted to use and disclose protected health information with the authorization of the research participants, or without individual authorization in limited circumstances.

* 1. Select which of the following is applicable to your research:

My research does not require access to individual health information and therefore HIPAA does not apply.

I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

I will be obtaining HIPAA Authorization from participants.

* 1. Appropriate Use for Research: Explain how you will ensure that only records of patients/participants who have agreed to have their information used for research will be reviewed.

We are using the CTSI to obtain medical record numbers for only those patients who were in the Executive Health program who underwent VO2max testing.

* 1. Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply). In the case of research involving sensitive data (including data that is sensitive but not covered by HIPAA), the protocol must include a robust security plan in compliance with the University’s [Data Security Policies.](https://policy.umn.edu/operations/phi) Review additional policies that may apply including the [University’s Data Security Classification](https://policy.umn.edu/it/dataclassification) and [Information Security policies](https://policy.umn.edu/it/securedata).

In the [BPIC](about:blank) data shelter of the [Information Exchange (IE)](https://www.ctsi.umn.edu/consultations-and-services/data-access-and-informatics-consulting/bpic)

Store  Analyze  Share

In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

Store  Analyze  Share

In REDCap (recap.ahc.umn.edu)

Store  Analyze  Share

In Qualtrics (qualtrics.umn.edu)

Store  Analyze  Share

In OnCore (oncore.umn.edu)

Store  Analyze  Share

In the University’s Box Secure Storage (box.umn.edu)

Store  Analyze  Share

In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact:

The path should be in the form of “\\vp.ahc.umn.edu\vp\Research\Study0004” If accessing PHI, HIPCO requires this information to verify the data are in a properly encrypted server.

In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices:

If accessing PHI, HIPCO requires and will confirm that devices used in this manner are properly encrypted.

Store  Analyze  Share

Other. Describe in detail the location and whether the data / specimens will be stored, analyzed, or shared, and in what ways.

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a SmartForm (iPhone or Android devices) that you have not already identified in the preceding questions

I will use a server not previously listed to collect/download research data

I will use a desktop or laptop not previously listed

I will use an external hard drive or USB drive (“flash” or “thumb” drives) not previously listed

I will use a mobile device such as a tablet or smartphone not previously listed

The data will be stored within the AHC-IE data shelter. Access will be restricted to only those individuals who have completed the required training, who are authorized to use the AHC-IE and who are registered with the IRB. Data will not leave the shelter unless fully de-identified per the policy of the AHC-IE.

After the de-identified data is downloaded from Breeze, this will be transferred to a zip drive and then to Anton’s personal laptop. From these devices Anton will analyze the data. Anton ultimately plans to share the de-identified data as part of the publication process. He plans to release the de-identified data and the computer code so other researchers can reproduce his analysis.

* 1. Consultants. Vendors. Third Parties.

NA

* 1. Links to identifiable data:

We do not need to create links to identifiable data.

* 1. Storage of Documents:

Data will only be shared with those listed on the IRB and will not be removed from the AHC-IE data shelter unless fully de-identified per the Safe Harbor method according to BPIC policy, or if a DUA is in place and the extraction meets AHC-IE policy.

Anton will generate electronic documents while analyzing this data. These will be kept on his personal laptop. Once finished with the analysis, the documents will be shared in a GitHub repository.

* 1. Disposal of Documents:

We do not have any plans to destroy the data. When the data are no longer needed, BPIC will remove access to the data and archive the data per BPIC policy.

# **Data/Specimen Management & Analysis**

* 1. Data Analysis Plan:

All data analysis will be completed using R and RStudio. We will calculate the VO2, %VO2max­, and time at both VT1 and VT­2 using all combinations of outlier determination, data interpolation, averaging methods popular in current literature for all exercise tests. We will create new predictor variables representing the combinations of the above methods. Using this we will perform a one-way, repeated measures ANOVA. If significant, we will perform post-hoc testing with all pairwise comparisons. Multiple comparisons will be corrected with the Benjamini-Hochberg procedure and alpha will be set to 0.05.

We will also calculate the LOA and bias for VO2, %VO2max, and time at both VT1 and VT2 for all combinations methods used to calculate these values. Density plots of the LOA and biases will be plotted to display the effect of these choices. The LOA and bias for a subset of combinations from the most popular data processing choices will be highlighted in the density plot and displayed in a table.

The similar research to date has only assessed the effect of averaging methods of VO2max, rather than on submaximal thresholds. It is therefore difficult to compute a power analysis to estimate the minimum number of records necessary. In addition, the number of participants in exercise research is generally low. Anecdotally many studies only recruit 8-12 people. By using the full number of records, we will therefore differentiate this from other studies.

* 1. Power Analysis:

We will not include a power analysis because of the lack of similar, previous studies. It is therefore difficult to estimate the effect sizes needed for power calculations.

* 1. Data Integrity:

The majority of data quality control has already taken place when the data was originally collected. However, Anton will make graphs of exercise tests to ensure that there were not issues with data collection. For example, a graph of VO2 vs. time where the VO2 drops close to 0 would likely indicate the mask worn during testing partially or completely fell off the patient during the test. This test would be discarded.

After entering the MRN into Breeze we will confirm that the patient has an exercise test on file in Breeze. If they do not, we will reenter the MRN. If still no exercise tests appear in Breeze, we will not copy exercise test data from that participant.

* 1. Existing Specimens (if applicable):

This study does not use biological specimens.

* 1. Specimen Storage and Access:

This study does not use biological specimens.

* 1. Data associated with specimens:

This study does not use biological specimens.

* 1. Plans for Identifiers on Specimens (if applicable):

Although the CTSI will provide us with a unique patient ID, the link from this ID to the MRN requires access to the secure data shelter. Since we are not removing any identifiable data from the secure data shelter, there should be no way of identifying patients based on their patient ID or exercise test file.

* 1. Release/Sharing:

We plan to publish our de-identified data as part of a GitHub repository when publishing the results of this study.

* 1. Destruction of Specimens*:*

Given our plans to share the de-identified data on a GitHub repository for research reproducibility, we do not plan to destroy the data.

# **Study Population**

* 1. Inclusion Criteria:

Participants must have completed a VO2max fitness assessment (Proc Code: 94017) and be patients in the UCSC IM Signature Program: FV:Department ID: 430000156.

* 1. Exclusion Criteria:

Those who opt out of sharing their data for research will be excluded.

* 1. Age Range:

There is no specified age range, but all those in the program to date have been adults, most of whom are in their 40’s or older.

# **Consent Process**

* 1. Consent Process (when consent will be obtained written or orally):

Participants have previously indicated if they wish to allow their data to be used for research purposes or not. We are not analyzing data from those who have previously opted out. We are therefore requesting a waiver of consent.

* 1. Waiver or Alteration of Consent Process (when consent will not be obtained):

We request a waiver of consent because the data required for this research concerns analyzing pre-existing exercise testing data. The maximal exertion exercise test itself is considered the riskiest part of this research and that has already taken place as part of the patient’s healthcare visit. Therefore, this study involves minimal risk. Also, the patients who have already undergone this exercise testing have previously indicated their desire to allow or to opt out of having their data be used for research purposes. It would be very time consuming and challenging to individually contact the approximately 250 patients to ask for consent for their de-identified exercise test data to be used for research. The Executive Health program is specifically designed to include executives and other upper management personnel. These individuals are often especially busy given their demanding jobs. Therefore, it may be more challenging than normal to reach these individuals for their consent to allow their data to be used for this research.

* 1. Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained):

NA

# **Risks**

* 1. Risks:

The only known risks a breach of confidentiality. For that to happen, MRNs or precise dates would need to be copied out of the secure server. However, this is unlikely because the MRNs and dates are only required to access de-identified data outside of the secure server.

BPIC services will be used to collect, store, and maintain the data and in accordance with their policies. All data will remain within the data shelter unless fully de-identified per the Safe Harbor method, or there is a DUA in place and the extraction meets the AHC-IE policy. Access will be restricted to authorized personnel only.  

# **Benefits**

9.1 Benefits:

Participants are not likely to receive any benefit from the proposed research. This research may in the long run benefit participants if it helps to more accurately prescribe exercise based on exercise tests. That assumes current participants continue to attend the Executive Health program and the study findings can be easily integrated into their patient visit. Society and other researcher will benefit from the knowledge gained.

**Appendix A. Types of Materials**

|  |  |  |
| --- | --- | --- |
| **Material Type** | **Material Quantity or Volume** | **Preservation Format (Specimens)** |
| Gas exchange test files | At least 1 per participant | A csv or txt file |
| De-identified patient and test characteristics file. E.g. sex, age at test, and year of test. | 1 summary data file | A csv or txt file |

**Appendix B. List of Identifiable Data Elements**

|  |  |
| --- | --- |
| **Identifiable Data Element** | **Included in this research study?** |
| Names | No |
| Dates, except year | Yes |
| Telephone numbers | No |
| Geographic data | No |
| FAX numbers | No |
| Social Security numbers | No |
| Email addresses | No |
| Medical record numbers | Yes |
| Account numbers | No |
| Health plan beneficiary numbers | No |
| Certificate/license numbers | No |
| Vehicle identifiers and serial numbers including license plates | No |
| Web URLs | No |
| Device identifiers and serial numbers | No |
| Internet protocol addresses | No |
| Full face photos and comparable images | No |
| Biometric identifiers (i.e. retinal scan, fingerprints) | No |
| Any unique identifying number or code | Yes |