**HUMAN RESEARCH DETERMINATION FORM**

**This form is only for use for projects not yet initiated or complete. The IRB does not issue retrospective determinations. If you are concerned that you have conducted human subjects research without prior approval from the IRB please contact our office at irb@umn.edu**

**INSTRUCTIONS:**

* Prior to initiation, investigators are required to submit and the IRB is required to review Human Research for which University of Minnesota, Gillette, or Fairview is engaged.
* Student-Investigators should create the ETHOS submission, but their Advisor submit the Determination Form (HRP-503).
* Review the [Investigator Manual (HRP-103)](https://drive.google.com/open?id=0B7644h9N2vLcOWtzU2FmSU5oS0U) for additional information about projects that may or may not require IRB review and approval:
  + “What if I’m not sure my project requires IRB review?”
  + “How does quality improvement differ from research?”
* If the activity involves any of the following, **STOP** and develop a protocol for IRB submission and review:
  + The use of a drug in one or more persons other than use of an approved drug in the course of medical practice.
  + The use of a medical device or a tobacco product in one or more persons that evaluates the safety or effectiveness of that device.
  + Data regarding subjects or control subjects submitted to or held for inspection by FDA.
  + Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA.
* The IRB Office uses “WORKSHEET: Human Research Determination” (HRP-310) to make its Human Research determinations. Please consult that worksheet as a guide for the information you provide in Section 1.0.
* Complete Section 1.0 below with details about your proposed activity.
* If you need a determination for a grant-only submission, e.g., Training Grant or Umbrella Grant, be sure to indicate that explicitly in that section.
* After completing Section 1.0, create a new study in ETHOS and upload the entire document in lieu of an Investigator’s Protocol and submit the study for IRB Office review.
* If, while reviewing this determination form, you discover that an activity is Human Research, consult the “Investigator Manual” (HRP-103) for further instructions.
* If you need assistance, ***Email or call the IRB at*** [*irb@umn.edu*](mailto:irb@umn.edu) *or  
  (612) 626-5654*

**PROJECT PLAN COVER PAGE:**

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| --- | --- |
| **Protocol Title** | CPET Data Processing |
| **Principal Investigator/Faculty Advisor** | Name: Christopher Lundstrom |
| Department: Kinesiology |
| Telephone Number: |
| Email Address: |
| **Student Investigator** | Name: Anton Hesse |
| Current Academic Status (**Student**, Fellow, Resident): |
| Department: Kinesiology |
| Telephone Number: 612-616-0944 |
| Institutional Email Address: hesse151@umn.edu |
| **Version Number/Date:** | Version 1. 4/11/2022 |

**REVISION HISTORY**

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| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
|  | 5/27/21 | Updated to clarify form no retrospective review. Only for use prior to initiation of research activities |  |
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NOTE: Leave this section blank for the initial submission. The revision history should be documented for modifications to approved studies.

# Description of Activity

Describe the project and identify what kinds of activities will be involved. **Delete the italicized instructions below when providing your information.**

* 1. **Purpose**  
     Describe the purpose, specific aims, or objectives of the project. For example, is the activity limited to program evaluation, quality assurance, or quality improvement activities designed specifically to evaluate, assure, or improve performance within a department, classroom, or hospital setting?

**Purpose**: The purpose of this project is to examine the effects of different data processing procedures on the automated calculation of submaximal thresholds from a graded exercise test. For example, altering the outlier criteria and data averaging methods change the automated calculation of these thresholds. This project seeks to quantify the effect of those different data processing choices on the calculation of submaximal thresholds.

* 1. **Procedures**Describe the procedures used to obtain information from the individuals with whom you will interact or intervene for this activity, including communication or interpersonal contact with individuals and physical procedures, if any. For example, will the project include interviews, surveys, or other assessments? Will the interview questions focus on policies, practices, and/or procedures (e.g. the collected data does not focus on personal opinion or private information)? Include the setting (location) for which the procedures will take place.

Patients in the Executive Health program at the Clinics and Surgery Center undergo cardiopulmonary exercise testing as part of their visit. There are no additional procedures beyond their normal visit.

* 1. **Data and/or specimens**Describe the data and/or specimens that you will gather about individuals, including names of datasets you will access and links to data sources.
     + **Data and/or Specimen Collection and Analysis**  
       Describe the data and/or specimens you will collect and how they will be analyzed.

The data has already been collected as part of each patient’s visit in the Executive Health program. The data are ventilatory variables from the cardiopulmonary exercise test, such as rate and depth of breathing. This data will be analyzed with a new package for the R statistical computing language, “gasExchangeR”, to process the data in different ways before calculating submaximal thresholds that are used in exercise prescription. For example, the data averaging method will be changed and the effect on the calculation of the submaximal thresholds will be recorded.

* + - **Data and/or Specimen Collection Method**Describe how you will obtain the data or specimens. (Are you obtaining them from another researcher? Are you pulling data from directly from a medical record? Are you pulling leftover samples from a lab?)

The data will be collected from the metabolic cart software used to collect the data. A summarized version of this data is exported to Epic and added to the patient’s medical record. However, the student investigator is of the understanding that the raw, unaveraged data is not directly tied to the medical record. Rather, that unaveraged data file resides within the metabolic cart software.

* + - **Identifiability of Data or Specimens**  
      Indicate whether the data or specimens you collect for this activity can be directly linked to individuals, (e.g., the dataset includes names), indirectly linked through a code (e.g., the dataset includes a code and you have the key to the code), or not linked at all to individuals (e.g., the dataset includes a code, but no one but the person giving you the data or specimens has the key to the code).

The unaveraged exercise test files are de-identified and the data is not coded.

*Is your data de-identified?* Visit the [Health Information Privacy and Compliance Office](https://www.healthprivacy.umn.edu/policies-procedures/creating-de-identified-data-set) on how to create a de-identified data set.

*Is your data coded?* Review OHRP’s [2008 Guidance on Coded Private Information and Specimens Use in Research](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html).