UNIVERSITY OF MINNESOTA

Twin Cities Campus

Human Research Protection Program
Office of the Vice President for Research

Room 350-2
McNamara Alumni Center
200 Oak Street S.E.
Minneapolis, MN 55455

612-626-5654
irb@umn.edu
https://research.umn.edu/units/irb

EXEMPTION DETERMINATION

May 23, 2022

Christopher Lundstrom

612-381-7970
lund0982@umn.edu

Dear Christopher Lundstrom:

On 5/23/2022, the IRB reviewed the following submission:

Type of Review:	Initial Study
Title of Study:	The effect of gas exchange data processing on the automated calculation of submaximal thresholds
Investigator:	Christopher Lundstrom
IRB ID:	STUDY00016110
Sponsored Funding:	None
Grant ID/Con Number:	None
Internal UMN Funding:	None
Fund Management Outside University:	None
IND, IDE, or HDE:	None
Documents Reviewed with this Submission:	• gas exchange data processing protocol, Category: IRB Protocol; • CTSI/BPIC consultation letter, Category: AHC-IE Application / Approval;

The IRB determined that this study meets the criteria for exemption from IRB review. To arrive at this determination, the IRB used "WORKSHEET: Exemption (HRP-312)." If you have any questions about this determination, please review that Worksheet in the HRPP Toolkit Library and contact the IRB office if needed.

This study met the following category(ies) for exemption:

- (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to

the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

The IRB, serving as the HIPAA Privacy Board, has issued a waiver of the requirement to obtain HIPAA Authorization to conduct research with records. This waiver is being issued because the IRB has determined that: (1) The description of the PHI for which use or access is included in the protocol summary and is necessary for the research; (2) the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals; (3) the research could NOT practicably be conducted without the waiver or alteration; and (4) the research could NOT practicably be conducted without access to and use of the protected health information.

Ongoing IRB review and approval for this study is not required; however, this determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these activities impact the exempt determination, please submit a Modification to the IRB for a determination.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the HRPP Toolkit Library on the IRB website.

For grant certification purposes, you will need these dates and the Assurance of Compliance number which is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003).

Sincerely,

Dylan Olson, CIP
IRB Analyst II

We strive to provide clear, consistent and timely service to maintain a culture of respect, beneficence and justice in research. Complete a brief survey about your experience.