

MODIFICATIONS REQUIRED TO SECURE “APPROVED” DETERMINATION

May 18, 2022

Christopher Lundstrom

612-381-7970
lund0982@umn.edu

Dear Christopher Lundstrom:

On 5/18/2022, 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:	None
Internal UMN Funding:	None
Fund Management Outside University:	None
IND, IDE, or HDE:	None

The IRB determined that modifications are required to secure approval for this submission. The modifications required and their reasons are listed here:

1. Please have Anton Hesse complete the Good Clinical Practice and Human Research Protections for Biomedical Study Teams - Basic Course.

You may not yet implement the changes proposed with this Modification; however, you may continue to conduct your study in the manner that it was approved prior to submission of this Modification.

Please make changes to your submission in ETHOS and re-submit when ready. When re-submitting, please provide a summary of the changes you made and how those changes address the required modifications above. For each modified document, please submit only a “tracked-changes” version. If approved and finalized, your tracked changes will be accepted automatically, so be sure to view your document with “No Markup” under the

Review tab in WORD prior to uploading it to ensure proper formatting. For additional guidance, please see the detailed job aids available in the “How to Submit” section of the [IRB website](#).

Sincerely,

Dylan Olson, CIP
IRB Analyst II