

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Human Research Protection Program
Office of the Vice President for Research

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April 12, 2016

Nicholas Lim
MMC 36 Mayo
420 Delaware St SE
Minneapolis, MN 55455

RE: "TAPS: Teaching About Paracentesis Safely"

IRB Code Number: **1601S83245**

Dear Dr. Lim:

The Institutional Review Board (IRB) received your response to its stipulations. Since this information satisfies the federal criteria for approval at 45CFR46.111 and the requirements set by the IRB, final approval for the project is noted in our files. Upon receipt of this letter, you may begin your research.

The IRB waives the requirement of informed consent for this medical record chart review, as allowed by 45 CFR 46.116 (d), because the research involves no more than minimal risk to the subjects, a waiver will not adversely affect the rights and welfare of the subjects, the research could not practicably be carried out without a waiver or alteration and, where appropriate, the subjects will be provided with additional pertinent information after participation.

You are approved to access 150 records from Academic Health Center Information Exchange. Please note that you may be required to present this letter when requesting access to records.

On March 2, 2016 the IRB approved the referenced study through March 1, 2017 inclusive.

The Assurance of Compliance number is FWA00000312 (Fairview Health Systems Research FWA00000325, Gillette Children's Specialty Healthcare FWA00004003). Research projects are subject to continuing review and renewal. You will receive a report form two months before the expiration date. If you would like us to send certification of approval to a funding agency, please tell us the name and address of your contact person at the agency.

As Principal Investigator of this project, you are required by federal regulations to inform the IRB of any proposed changes in your research that will affect human subjects. Changes should not be initiated until written IRB approval is received. Unanticipated problems or serious

unexpected adverse events should be reported to the IRB as they occur. Notify the IRB when you intend to close this study by submitting the Study Inactivation Request Form.

The IRB wishes you success with this research. If you have questions, please call the IRB office at 612-626-5654.

Sincerely,

Clinton Dietrich, MA
Research Compliance Supervisor
CD/bw

CC: Andrew Olson