



The University of Vermont

RESEARCH PROTECTIONS OFFICE

Determination of "Not Research"

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<p>Committees on Human Subjects Serving the University of Vermont and the UVM Medical Center</p>	<p>Email</p>	<p>213 Waterman Building 85 South Prospect Street Burlington, Vermont 05405 (802)656-5040 ph www.uvm.edu/rpo/</p>
	<p>Print</p>	

CERTIFICATION

TO: J. Horbar

DATE OF CERTIFICATION: Monday, December 10, 2018 - 12:58

SUBJECT: The Ins and Outs of Neonatal Care

Based upon answers to the self-determination tool, this project does not require IRB review because it does not meet the definition of a "research" activity under the regulatory definition. According to 45 CFR 46.102(d), the definition of "research" is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Projects that are not a systematic study or are not intended to contribute to generalizable knowledge, e.g. quality assurance, quality improvement, program evaluation, or public health practice, do not require IRB review.

This certification can be provided as documentation that this project does not meet the definition of research. Public presentations, academic curriculum vitae, publications, etc., with a planned statement similar to *"According to the policy defining activities which constitute research at the University of Vermont/University of Vermont Medical Center, this work met criteria for operational improvement activities exempt from ethics review."*

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