SUBMITTED BY: **STEPHEN M. LANIER, PH.D.**
VICE PRESIDENT FOR RESEARCH

REPORT ON WAIVERS APPROVED
TO BOARD STATUTE 2.41.01.140

BACKGROUND

Two research projects required a petition to waive Statute 2.41.01.140 because of review restrictions on publishing the research results. This waiver has been approved by the Vice President for Research to allow acceptance of the relevant grant or contract, acting in accordance with the University's research policy on restricted and proprietary research.

OVERVIEW

Xeragenx, LLC

This waiver allowed acceptance of a sub-contract award, Intrinsic Factor Mediated Detection of the Cubilin Receptor, funded to Syracuse University by Xeragenx, a plant sciences company that develops and commercializes advanced prescription and nutritional products for unmet therapeutic needs. The subcontract will explore the function of Cubilin (CUB) within the kidneys to bind ligands such as albumin and holo-transferrin for recirculation. The hypothesis of the Project is that a radio-probe of B_{12} (rB_{12}), when bound to hIF (IF-rB_{12}) and systemically delivered, will target CUB and allow for the specific targeting of CUB positive cell lines *in vivo*, producing high injected dose per gram (ID/g) relative to background and excellent signal to noise in vivo. It is also likely that such an approach could be readily adapted to target treatment of cancerous CUB positive tumor lines such as renal cell carcinoma (RCC).

At the conclusion of this project, the research team will have collected proof-of-principle evidence supporting both hypotheses and validated the future exploration of hIF as a pharmaceutical and pharmaceutical platform technology in these areas.

The project will be led by Nerissa Viola-Villeagas, Ph.D. assistant professor, cancer biology graduate program. This project required a waiver to Board Statute 2.41.01.140 because all publication submissions on this grant require approval from Syracuse University, the lead institution on this grant.

Vertex Pharmaceuticals

This waiver allowed acceptance of a sub-contract award, Phase 2a, Randomized, Double-blind, Placebo-controlled, Incomplete Block, Crossover Study to Evaluate the Safety and Efficacy of VX-371 in Subjects Aged 12 Years or Older with Cystic Fibrosis, Homozygous for the F508del-CFTR Mutation and Being treated with Orkambi. The project will evaluate the safety and efficacy of treatment with VX-371 in hypertonic saline compared to hypertonic saline alone in subjects with cystic fibrosis who are over 12 years old, homozygous for the F508del-CFTR mutation, and being treated with Orkambi.

The project will be led by Dana Kissner, M.D., associate professor of Medicine and director of the Adult Cystic Fibrosis Center at Harper University Hospital. This project required a waiver to Board Statute 2.41.01.140 because all resulting publication submissions and presentations require a 120-day publication delay to allow for a coordinated approach from all of the sites participating in this study.