January 17, 2017

To Whom It May Concern:

This letter serves as verification that St. Vincent Hospital and Health Care Center, Inc. (St. Vincent) Institutional Review Boards (IRBs) operate in accordance with Federal Law 45 CFR Part 46. The St. Vincent IRBs also assures that all activities related to human subject research, regardless of funding source, will be guided by the ethical principles in the Belmont Report.

In addition, St. Vincent complies with all U.S. Federal laws, Indiana State laws, and ethical principles that relate to human subject research and healthcare.

The St. Vincent IRBs operate with approved Federal Wide Assurances under the institution name STVIRB FWA Number 00001631. The FWA was granted on 8/14/2014 and expires on 8/18/2019.

St. Vincent operates two (2) IRBs under the following names and numbers: STVIRB#1 IRB00001947 and STVIRB#2 IRB00004956. Membership of these boards is constituted in compliance with Federal regulations [45 CFR 46.107 and 21 CFR 56.107]. To preserve the integrity and confidentiality of the IRB process, St. Vincent does not distribute its IRB membership roster. The IRB meetings are confidential, and all Board members are required to sign non-disclosure agreements.

St. Vincent also operates an Institutional Biosafety Committee that is registered and in compliance with the Office of Biotechnology at the US Department of Health and Human Services.

Please feel free to contact St. Vincent IRB Office at (317) 338-2194 if you have questions.

Sincerely,

Tina G. Noonan, MBA, CHRC, CIP
Executive Director of Research
St. Vincent Hospital and Health Care Center, Inc.