

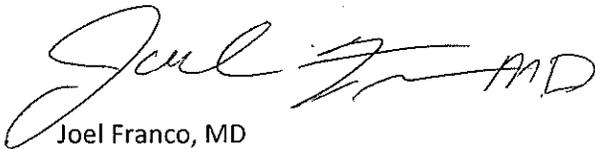
Institutional Review Board Statement

IRB approval was not required for this case report. Indiana University School of Medicine's Policy is listed below.

Section II: SOPs Section II – Confidentiality and Privacy 34

3.3.10.2 Use of a patient's PHI or biological sample for a case report for **education/teaching purposes** is deemed health care operations and does not require IRB approval or authorization or waiver of authorization. Care should be taken to ensure that no patient identifiers are used.

3.3.10.3 Use of a patient's PHI or biological sample for a single case report for publication does not require IRB approval or authorization/waiver of authorization, providing the patient was treated by the person reporting the case(s) and the information is de-identified. **HOWEVER, should there be two or more cases, any systematic study such as a query of any database for additional cases, or analyzing serum by additional assays, etc., then this becomes RESEARCH** and requires IRB approval, and must be conducted using one of the mechanisms as detailed in this SOP (Sections 5.5 through 5.9)



Joel Franco, MD

1/14/15