



Holy Cross Hospital  
Orthopedic Research Institute

5597 N. Dixie Highway  
Fort Lauderdale, Florida 33334  
Phone: (954) 958-4800 Fax: (954) 229-8698  
[www.holycrossorthopedics.com](http://www.holycrossorthopedics.com)

Study no. **2017-001-PD**

Study Title: **Effect of Opioid Dependence or Abuse on Prolonged Opioid Use after Shoulder Arthroplasty: Analysis of a Single Private Payer**

Thank you for the submission of your study. It is the policy of Holy Cross Hospital (HCH) that a PearlDiver study does not require review by the IRB.

PearlDiver has partnered with Comprehensive Health Insights to integrate Humana's full claims database in to the PearlDiver research program. Research is conducted over the full set including commercial and Medicare advantage populations. While de-identified and HIPAA compliant, this research set is fully capable of longitudinal research based upon unique patient identifier codes. Research can be performed utilizing any one or combination of identifiable fields on the claim record processed by Humana. Fields include but are not limited to; ICD-9 & ICD-10 diagnosis coding, DRG procedural coding, ICD-9 & ICD-10 procedural coding, CPT procedural coding, prescription NDC coding, lab record LOINC coding, discharge status, demographic, physician specialty, and geographic region or state.

The Holy Cross Hospital Research Office received your request (dated 11/01/2017), concerning a study you wish to publish and or present. The Executive Director of Research has determined that IRB review is not required for this activity. The Investigator must inform the Research Office if a journal does not accept the IRB's decision. The issue will then be brought to an IRB Meeting for resolution.

As submitted your study does not include any protected health information for HIPAA purposes. Any use or disclosure of PHI must be authorized by the patient, or, if the patient is deceased, the patient's family. Based on your representations there is no PHI being used that would require additional HIPAA review.

Thank you for your submission

Paul Papagni, JD  
Executive Director/Research