

# Inconsistency among Hospital Institutional Review Boards in the National Children’s Study: A Review of Experiences with 21 Institutional Review Boards Encountered by The Children’s Hospital of Philadelphia’s Study Center.

## Introduction:

Clinical research in the United States is governed by Federal, State, and Local laws in addition to Institutional Review Boards (IRB). Inconsistent interpretation of regulations by local entities may lead to regulatory discrepancies, increased expenditures and the delay of Study implementation. The Children’s Hospital of Philadelphia Study Center (CHOP SC) encountered these inconsistencies when submitting the National Children’s Study’s protocol (NCS) to local area birth hospitals IRBs for approval of data collection activities.

## Methods:

From January 2009 until July 2011 the CHOP SC captured operational data for each IRB, including the time required for IRB approval and IRB determination. All IRBs were approached with a consistent method developed at the CHOP SC. This included the required protocol information, supplemental outreach materials and a customized multi-pronged communication strategy.

## Results:

Of the 21 IRBs approached in relation to the Montgomery County, PA NCS location; 5 determined that they were not engaged, 8 deferred, 9 reviewed the protocol (full and/or expedited) with two requiring a local Principal Investigator. These determinations required 2 to 10 months to finalize and were directly correlated to the category of IRB review performed.

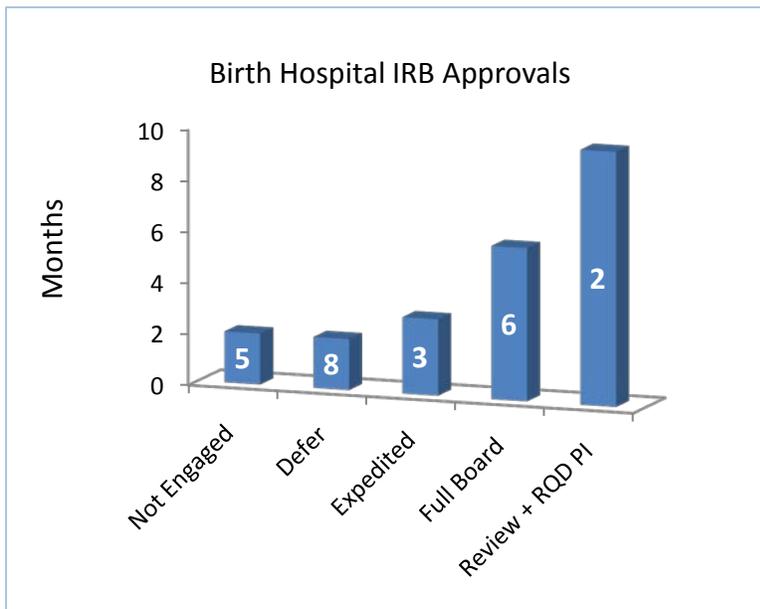


Table 1.0  
IRB Review Determinations / Time

**Conclusions:**

The type of IRB review and extent of time required varied considerably by individual institution as seen in Table 1.0. These discrepancies directly affected CHOP SC expenditures and timelines. A new model of regulatory oversight for National, Multi-center, Federally sponsored and IRB sanctioned clinical research will support the feasibility of conducting future clinical research endeavors.