

## INSTITUTIONAL REVIEW BOARD SOP 205: Special Populations - Children

## POLICY

When a proposed research study involves children and is supported or conducted by HHS, an Institutional Review Board (IRB) must take into consideration the special regulatory requirements that provide additional protection for the children who would be involved in the research. If the proposed research involves FDA-regulated products, then FDA's parallel regulations would apply.

However, at Decatur Memorial Hospital, the patient population is such that children are not enrolled in research. They cannot be enrolled since the protocols activated by the Investigator are written almost entirely with adults in mind. Furthermore, there are no pediatric researchers or oncologists on campus.

## SCOPE

This SOP applies to all pediatric research.