The YODA Project
Research Proposal Review - Final
(Protocol #: 2019-3943 )

Reviewers:
☒ Nihar Desai
☐ Cary Gross
☐ Harlan Krumholz
☒ Richard Lehman
☐ Joseph Ross

Review Questions:

1. Is the scientific purpose of the research proposal clearly described?  
   Yes

2. Will request create or materially enhance generalizable scientific and/or medical knowledge to inform science and public health?  
   Yes

3. Can the proposed research be reasonably addressed using the requested data?  
   Yes, or it's highly likely

4. Recommendation for this data request:  
   Approve

Comments:

This is a useful secondary analysis of the REACH trial, determining whether serum infliximab concentration is associated with improved outcomes among pediatric patients with moderate-to-severe Crohn’s disease. My only concern is whether serum infliximab concentrations were collected at weeks 2, 6 and 10, as needed by the investigators. This should be confirmed with the clinical trial team at Janssen.