

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

**Reviewers:**

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

**Review Questions:**

**Decision:**

- |                                                                                                                                     |                            |
|-------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| 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.