

**The YODA Project**  
**Research Proposal Review - Final**  
**(Protocol #: 2014-0334 )**

**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                    |

**Decision:**

**Comments:**

We noticed that you requested full CSRs for this project. The YODA Project recommends individual patient-level data for this; the full CSRs will most likely not contain all of the information you need to complete your research. This decision is at your discretion.

The authors could consider taking advantage of the controlled nature of the requested study data. That is, they could compare the change in weight between male and female patients in the treatment vs. the control groups. This 'difference in differences' approach could help to account for any trends in weight over time that might be related to sex, but not to IFX treatment.