

The YODA Project
Research Proposal Review - Final
(Protocol #: 2015-0612)

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:

The authors should consider incorporating the hierarchical nature of the data into their analytic plan (i.e. the patients are clustered into the distinct RCTs).

The study will evaluate the impact of obesity on disease course and response to biologic therapy in IBD patients. The primary outcome is clinical remission, defined as CDAI < 150 for adults and PCDAI < 10 for children for Crohn's disease patients. Both CDAI and PCDAI have a weight component score, where lower weight compared to the standard weight is assigned to a worse CDAI/PCDAI score. A heavier weight compared to the standard weight is given a better weight component score in CDAI/PCDAI. Therefore, the outcome measurements for the endpoints have limitations to evaluate the negative impact of obesity on disease. One may consider removing the weight component from PCDAI/CDAI score and adjust the CDAI/PCDAI cutoffs in clinical remission definition.