

The YODA Project
Research Proposal Review - Final
(Protocol #: 2019-4067)

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 an interesting study and has great potential value. However, it would be helpful to get clarity on which of these studies will be used to evaluate early treatment endpoints among pediatric patients. Further clarification would be useful because the resources required to make 40+ trials available, as opposed to a handful, are not insignificant.