

The YODA Project
Research Proposal Review - Final
(Protocol #: 2015-0539)

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:

Applicant describes that data has also been requested from ClinicalStudyDataRequest.com (GSK-led site) and from Shire Pharmaceuticals. Not clear how many additional data sources were requested, whether accounts will be able to be merged within SAS data sharing platform, or whether project could be successful if only data from NCT00866996 can be used.

The investigators seem to want the clinical assessment data from this trial, especially ADHDRS-IV, to help to validate a new assessment system (IRT). I am not sure that this is feasible.