

The YODA Project
Research Proposal Review - Final
(Protocol #: 2022-4975)

Reviewers:

- Nihar Desai
- Cary Gross
- Harlan Krumholz
- Richard Lehman
- Joseph Ross
- Joshua Wallach

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:

1. In the 'main outcome measure' section, investigators listed 6 outcomes for UC trials and 8 outcomes for CD trials, and then listed addition remission and response-based outcomes in the 'main predictor/independent variable' section. However, given the proposed objective, the main predictor/independent variable should be written as "concomitant baseline use of steroids, aminosalicylates, immunosuppressants, PPIs, antidepressants, or opioids."
2. Please clarify if each concomitant medication will be analyzed in separate analyses (n=6) or somehow aggregated into a single analysis (if so, please explain).