

The YODA Project
Research Proposal Review - Final
(Protocol #: 2015-0416)

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:

The authors may want to consider testing for an interaction between treatment arm and baseline fracture "risk factors" in their Aim 1 analysis, in order to determine if there are specific characteristics that moderate the risk associated with canagliflozin.