The YODA Project
Research Proposal Review - Final
(Protocol #: 2019-4134 )

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:
Investigators request one trial for inclusion in their network meta-analysis, but name multiple other trials. Access to participant-level data is granted through a remote desktop connection to a secure platform. All work on participant-level data must take place within the secure platform. Participant-level data cannot be exported from the platform. Researchers can upload additional data sets to the secure platform, provided they have the rights/license to do so. Supporting documentation, such as CSRs, as well as summary-level analyses, can be exported from the platform.