The YODA Project
Research Proposal Review - Final
(Protocol #: 2021-4818 )

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:
Interesting specifically-defined proposal to access full CSRs for additional information to add to a meta-analysis that is already under review at a journal. A reviewer asked for 3 specific pieces of data which the requesting investigators hope to ascertain from the CSRs (see below). Hopefully, this information is available!

NCT02417064: remission at 24 hours (N, %) for placebo, 56mg esketamine and 84mg esketamine groups.
NCT02418585: remission at 24 hours (N, %) for placebo and flexibly dose esketamine.
NCT02918318: baseline MADRS (mean and standard deviation), remission at 24 hours (N, %), remission at study endpoint (N, %) for all groups- placebo, 28mg esketamine, 56mg esketamine, 84mg esketamine.