The YODA Project
Research Proposal Review - Final
(Protocol #: 2021-4568)

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:

Interesting study to measure the interaction between change in psychosis and liability to develop motor side effects with antipsychotics using data from 15 clinical trials of INVEGA®, INVEGA SUSTENNA®, and RISPERDAL®. Authors describe their analyses as primarily descriptive with mixed model regression modeling to understand the association between change in psychosis and motor side effects, seemingly unadjusted for other covariates (and no other covariates are listed). However, I would expect these analyses would be stronger if the mixed model regression modeling included adjustment for sociodemographic and/or clinical covariates (that should be prespecified), particularly if any were known to be associated with likelihood of either success in psychosis treatment or in developing motor side effects.