

**The YODA Project  
Research Proposal Review**

The following page contains the final YODA Project review  
approving this proposal.

**The YODA Project**  
**Research Proposal Review - Final**  
**(Protocol #: 2020-4305 )**

**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:**

No additional comments.

**The YODA Project  
Research Proposal Review**

Revisions were requested during review of this proposal.  
The following pages contain the original YODA Project review and  
the original submitted proposal.

**The YODA Project**  
**Research Proposal Review - Revisions Requested**  
**(Protocol #: 2020-4305 )**

**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?  | Unsure, further clarification from requestor is needed |
| 4. Recommendation for this data request:  | Not Approve  |

**Comments:**

Upon final review of the Monolix software, it has been determined that the Monolix software cannot be added to our secure platform. However, your data request indicates that RStudio can be used to perform some analyses. If you are interested in pursuing this data request using R, please update the statistical analysis plan to reflect any changes to the analysis plan and remove the request for Monolix.