

**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 #: 2023-5316)

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:

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 #: 2023-5316)

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? | No |
| 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: | Not Approve |

Comments:

1. Our reviewers had trouble understanding the exact purpose of the research study. At different points in the research proposal, the objective is stated differently (Assessment of ISS-R2 as a Prognostic Indicator; validate the ISS-R2 and compare its predictive capacity with insights from prior literature cohorts; assess capacity of the predicting prognostic events of the Revised International Staging System(ISS-R2) ... and so on). Their impression is that the study's objective is to examine ISS-R2 as a prognostic/predictor variable of patients' outcome(observed mortality and PFS) among those undergoing anti-CD38 chemotherapy. Is this correct?
2. Could you make the purpose of the research study clearer, removing aspects of the proposal that address an 'external validation' or use of the literature, and reviewing the proposal closely to ensure that it is written as clearly as possible?