

**The YODA Project**  
**Research Proposal Review - Final**  
**(Protocol #: 2020-4236 )**

**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 proposal. Would strongly suggest the authors take advantage of both arms of this RCT and characterize blood pressure changes among patients randomized to receive Ibrutinib and Chlorambucil, with interaction analyses or stratification by patients' known history of hypertension.

The increments for categorical increases in BP seem very large (10mm Hg diastolic, 20mg systolic) and I'm not sure what they add to the continuously variable BP data. Given that the latter will be part of the analysis, however, I would not see this as an objection to approval.