HRPO#:

Principal Investigator:

Title of Research Project:

1. **Should this study stay open with PRMC?**

**1.a. Is this study permanently closed to accrual?  Yes  No  N/A**

**1.b. Are all participants off the intervention?  Yes  No  N/A**

**STOP!**

* + - **If you answered “NO” to one or both questions, please continue completing this form.**
    - **If you answered “YES” to BOTHquestions or if this is a *retrospective* study and you answered “YES” to question 1.a. then please complete the *PRMC closure form* instead. Once the PRMC closure has been approved, you are not required to submit amendments or renewals for PRMC review.**

1. **Are any of the PRMC co-chairs collaborators on this trial?**

**REMINDER 🡪 If yes, please ensure they are listed in OnCore as protocol staff.**

**Yikyung Park**

**Clifford Robinson**

**Brad Kahl**

**Julie Margenthaler**

**Meagan Jacoby**

**None**

1. **What is the current accrual status? (check one)**

**Pending/Not Yet Open to Accrual**

**Open to Accrual**

**Suspended**

**Closing to Accrual (with this submission)**

**Previously Closed to Accrual as of Date:**

1. **List Current Approved Versions:**

|  |  |  |
| --- | --- | --- |
| **Document** | **Version Date** | **Version Number** |
| Current Protocol |  |  |
| Current Informed Consent |  |  |
| Current IB |  |  |

1. **Do the changes significantly alter the study design, objectives, and/or statistical analyses?**

**Yes**

**No**

1. **Please use the box below to list/describe all updates with this submission.**

**REMINDER 🡪 Study teams must update the OnCore record with any changes listed below.**

**Study Title Change – Specify new title:**

**Accrual Number Updates – Specify accrual updates:**

**PI Update – Specify new PI:**

**Disease/Diagnosis Update – Specify disease/diagnosis added or removed:**

**Other – Use box below to summarize or attach rationale if more space is required:**

|  |
| --- |
|  |

1. **Please check box of revised document(s) and list applicable version info:**

**The submission must include:**

1. **A separate Summary of Changes document with rationale for ALL protocol and IB changes.**
2. **Red-lined (tracked changes) versions of the Protocol, Consent Form, and IB.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Document** | **Version date** | **Version number** | **Check if red-lined (tracked changes) version NOT provided by sponsor** |
| New Protocol |  |  |  |
| New Informed Consent |  |  |  |
| New IB |  |  |  |

**Please note all documents being revised must be submitted to PRMC. Each document should be sent as an individual PDF. Please see https://siteman.wustl.edu/research/clinical-research-resources/protocol-office-prmcqasmc/ for further information.**