



March 31, 2021

RE: IRB Policy on Reporting Outcomes of Independent Safety Monitoring Reviews

To Whom It May Concern:

This letter serves to inform the research community and sponsors of the expectations of the University of Pennsylvania's Institutional Review Board (IRB) for submission of data safety monitoring committee reports (i.e. DSMB/DSMC/etc.). In general, the IRB expects these reports are submitted in a timely manner. This includes reports that recommend continuation of the study without modification.

Reports that include commentary which require a response or necessitate action on the part of the study team or sponsor must be accompanied by a response to any issues noted in the report.

It is important that the study team submit the DSMB reports to the IRB in real time so that the IRB may assess the appropriateness of study continuation. Any reports not submitted in real time must be provided with the annual request for continuing approval. However, failure to submit in real time will be raised to the Investigator's attention in their annual continuing approval letter and may require additional follow-up.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: <https://irb.upenn.edu>.

Thank you for your cooperation.

Sincerely,

Jessica L. Yoos, MA, M.Phil, CIP
Director, Human Research Protections