**GDPR Notice:**

In general, investigators will not be collecting or processing personal data on individuals located in the EU as part of their participation in this study. As a result, the GDPR is not applicable to research activities at VU or VUMC and the VUMC IRB is not in a position to approve the proposed changes to the consent form. These changes will be removed during pre-review. We do note that the previously approved consent document is written in such a way to confirm that subjects have freely and explicitly given specific, informed, and unambiguous written consent to the collection and processing of their data.

If a sponsor wishes to provide a separate notification to subjects, the sponsor may create a separate privacy notification for use at our site that is (1) distinct from the consent document; (2) does not include signature lines; and (3) does not reference our privacy officer as a contact for questions about GDPR. Questions should be directed to a contact provided by the sponsor.