CARILION CLINIC
Institutional Review Board

March 30, 2021

To: Peter Apel
Re: IRB Approval for Protocol #IRB-19-616, When can patients safely drive after rotator cuff repair?

Change Approval Date: 03/30/2021
Expiration Date: 10/07/2021

The Carilion Clinic Institutional Review Board (IRB) approved the Modification to the above referenced study. The approved Modification includes:

- The Removal of Joshua Edwards from the research team as well as the Addition of Mary Metrey to the research team.
- The Approval of the Revised External Research Team document reflecting these changes.

This approval is limited to the activities conducted by the research team members as described in the approved version of the IRB Application. Modifications may not be initiated without prior IRB review and approval except where necessary to eliminate apparent immediate hazards to human participants.

If this modification involved a change to the consent form, the IRB has issued a consent document(s) stamped with the modification approval date. The approval for the modified consent document will last the life of the study, or until it is amended; whichever comes first. It is the responsibility of the principal investigator and the research study team to ensure they are using the most current version of the consent form. It will also be the responsibility of the principal investigator and the research study team to ensure that no participant is enrolled if the expiration date for the study's IRB continuing review has been exceeded.

All research activities must cease the day before the Expiration Date if the study has not been reapproved by the IRB. If this study is expected to extend beyond one year, please submit a continuing review request at least 45 days prior to the expiration date. HHS regulations at 45 CFR 46.109(e) require that continuing review of research be conducted by the IRB at intervals appropriate to the degree of risk but not less than once per year. The regulations make no provision for any grace period extending the conduct of the research beyond the Expiration Date. Once research activities have been completed, please submit a closure form least 30 days prior to the Expiration Date.

In conducting this study, you are required to follow the requirements described in INVESTIGATOR GUIDANCE: Investigator Obligations (HRP-800), located on the IRB website.

The Carilion Clinic Institutional Review Board would like to thank you for the opportunity to review this protocol. We wish you the best and look forward to learning of your results. If you have any questions, please do not hesitate to contact the IRB at tharmon@carilionclinic.org or at 540-224-5883.