**TRIAL IMPACT ASSESSMENT**

**PROTOCOL TITLE:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Did your feedback result in any changes to the reviewed protocol and what do you see as the significance or impact of these changes?**

*If yes, please explain here (e.g., investigators agreed to expand inclusion criteria to participants ≤ 15 years old):*

**How likely is it that this change would have happened without your influence?**

*Unlikely*

*Somewhat likely*

*Very likely*

**Did any aspects of your feedback not result in a change to the reviewed protocol?**

*If so, did the investigators provide a rationale for not changing the protocol per your suggestion?*

**Are there any points of follow-up with the investigators?**

*If yes, please explain here:*

**Are there any lessons to note from this protocol review?**

*If yes, please explain here:*