**Project Title:** <insert official title of clinical trial>

**NCT Number:** <insert NCT number>

**Date:** <insert date document was last revised>

**Study Protocol**

\*NOTE\*: This is guidance on how to structure your Protocol Document and are not meant to serve as requirements for this document.

<insert the purpose of the trial>

<insert the aims of the trial>

<insert the enrollment (anticipated and actual)>

<insert the procedures conducted during trial>

**Statistical Analysis Plan**

<insert discussion about types of analyses performed>

<insert reasoning behind choice of analyses performed>