

## Executive Summary of Changes

The project team thanks the reviewers for submitting their comments and providing a number of useful suggestions for the study design protocol. This summary document highlights the changes made to the TC-B5 Protocol, *“Synthetic Mid-Urethral Slings for Stress Urinary Incontinence in Women,”* in response to the public comment period. Throughout the protocol, the version number changed from 1.0 to 2.0, and the date changed from May 1, 2020, to July 31, 2020 in the title page, synopsis, headers, and footers.

This document intends to highlight the more substantive changes made to the study protocol.

First, we added additional background, references, and justifications for the project. This included a few recent systematic reviews and meta-analyses that help frame the current state of the literature.

We removed redundant text in many parts of the proposal. This was an artifact of transformation from the original project proposal as submitted to the template that NEST requires for protocol submission, in which some pieces of information were duplicated to respond to template elements.

We conducted extensive work on updating the appendix document, providing additional value sets for variables, and clarifying which variables were separate, further describing certain variables. However, we anticipate even with these edits that additional changes will be made during data transformation and data quality checking process, as this will provide a more robust starting document for data definitions.

In the statistical method and study design sections, additional clarifications and explanation regarding surgical approach details were added. This was done to ensure that a wider audience would understand the importance and distinguishing characteristics between these surgeries.

In response to data quality assessment concerns, all sites agreed to a small volume of chart review to help assess how well the data transformation process approximated the patient as recorded in the EHR. This was added in the study procedures section.

We also clarified the overall study design with regards to how non-mesh SUI surgeries would be utilized in this project. Specifically, clarifications were added to explain that they would be analyzed separately and not directly compared.

Finally, we have added a section for all the clinical experts at each site who have participated in the study protocol generation and iteration.