TEEN-BESTrial – Serious Adverse Event Procedure

- ✓ All AEs and SAEs must be reported in the eCRF during the entire follow-up period. If a participant no longer participates in the trial, still all AEs and SAEs must be reported.

- ✓ SAE forms must always be signed by a physician. You can do this on paper by providing the signature of the physician at the bottom of the form or digitally in Research Manager with the button “Save as complete”.

- ✓ SAEs must be reported to the coordinating researcher (D.S. Bonouvrie - MD) within 24 hours by e-mail: danielle.bonouvrie@mmc.nl, including a fully completed SAE reporting form (via Research Manager or on paper (see SAE form)).

- ✓ The following SAEs do not have to be reported within 24 hours, but they must be documented in the eCRF. These will be reported to the REC every six months.

    - Regular postoperative complications without significant impact on the participant's health:
        - Wound infection
        - Bleeding or hematoma without re-intervention
        - Pneumonia and urinary tract infection

- ✓ Death must be reported immediately to the principal investigator during the entire follow-up by email; bariatrics.resurge@mmc.nl