Recommendations for ppts of special interest

- The following participants will be strongly advised to discuss their participation with their practitioner/ health provider and/or the Sisonke safety desk and/or the site PI:
  - History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.
  - Participants who are thought to have suffered a neurological adverse event considered related to the priming J&J vaccine.
  - Participants reporting a non-infective SAE within the first 28 days following the priming dose of J&J vaccine in the Sisonke 3B trial
- We note that international reports of TSS have not identified a risk factor, nor does there appear to be any prothrombotic state that indicates a risk factor for this immune response.
- Nevertheless, the Sisonke study will enrol the following participants **only** after consultation and approval of the study Protocol Safety Review Team (PSRT). (See process below).
  - Chronic history of severe clotting disorders
  - Participants who suffered a thromboembolic adverse event following the priming J&J vaccine.
  - These individuals may be commenced on short term prophylactic coagulation if deemed appropriate after consultation with a member of the Sisonke PSRT .