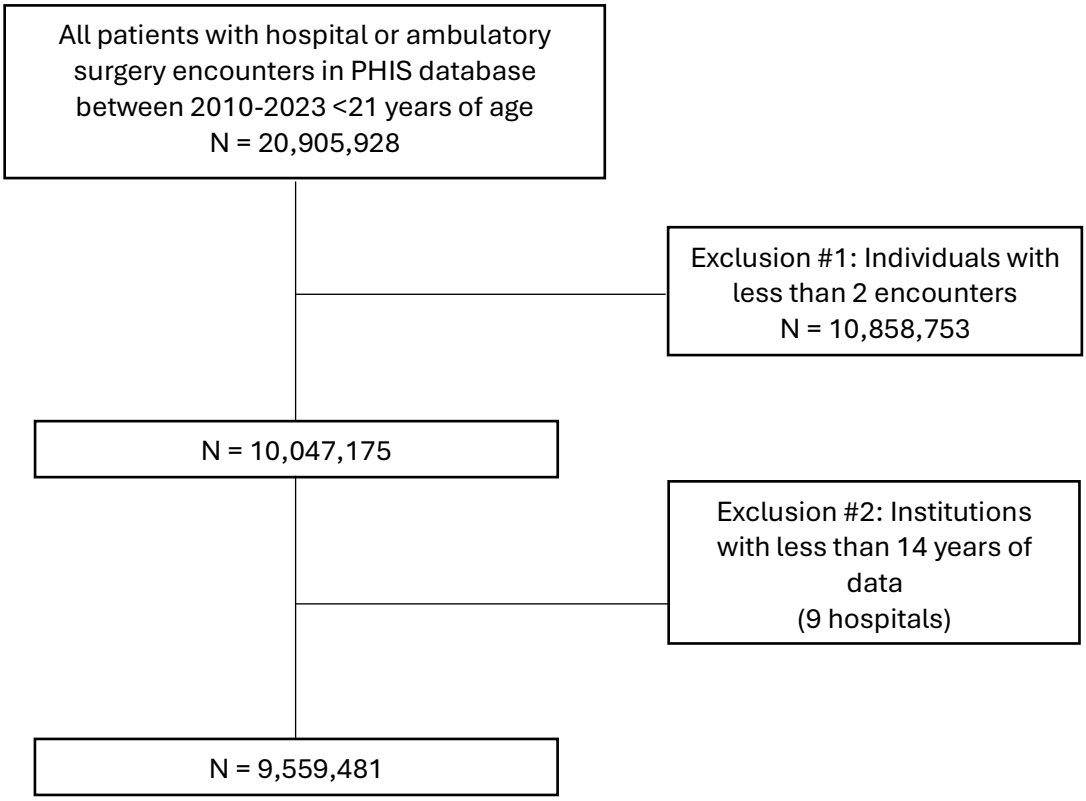Figure 1: CONSORT Diagram