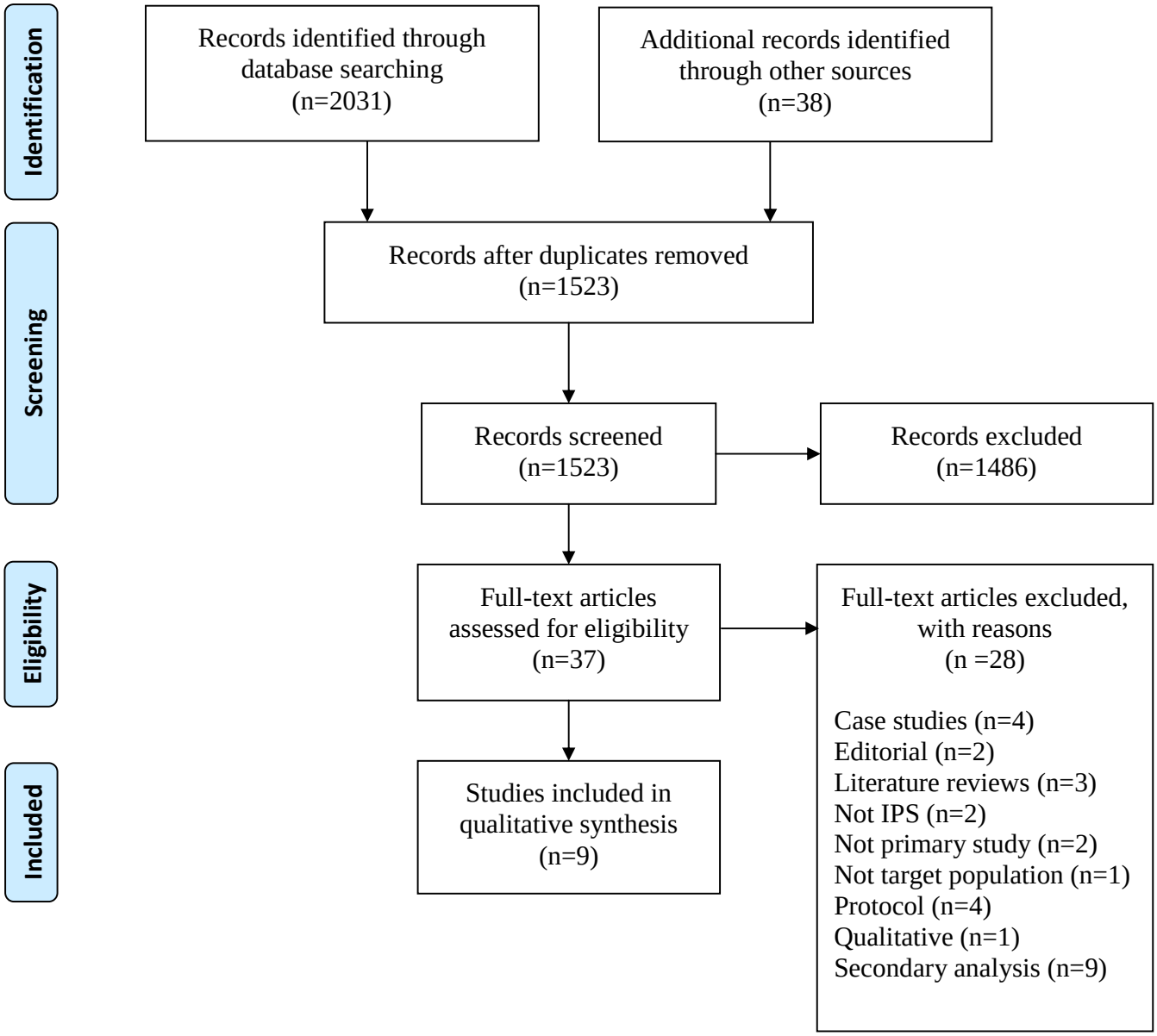ONLINE SUPPLEMENT: Study Flow Diagram