

## **The Use of Standard Operating Procedures (SOPs) in Clinical and Translational Research Centers (CTRCs)** By VARSHNI NANDAKUMAR, Amanda Gonzales, Noah Federman, MD

Clinical and Translational Research Centers (CTRCs) are integral to the clinical research infrastructure. CTCRCs play an important role in developing standard operating procedures (SOPs), which are uniformly written documents that provide step-by-step instructions on performing clinical, operational, and quality check procedures. However, each CTCRC across the nation is responsible for producing its own SOP library, and thus significant variations between CTCRC SOP libraries exist. Additionally, the onset of the COVID-19 pandemic has led to rapid modification of already-existing SOPs and has contributed to the increase in SOP library diversity. Due to these variations, there is no existing method to quantify the effectiveness of SOPs. In this project, CTCRC SOPs from academic medical centers across the nation and federal SOP databases were researched to quantify similarities between CTCRC SOPs. From these similarities, a series of three criteria were developed to measure the effectiveness of SOPs in clinical research environments. Because these criteria are based on the prominent similarities amongst the numerous categories of SOPs, they can be used as a universal check on SOP effectiveness. This will provide CTCRCs in the future with a more uniform direction when modifying or developing SOP libraries.