Purpose:
To document the process for reporting accrual to research projects involving human subjects for all studies not entering participants directly through the Clinical Research Shared Service.

Author:
Revised by SOPRC.

Target Audience or Responsibilities:
Members of the University of Arizona Cancer Center and collaborators conducting research related to human subjects.

Process Steps:
1) All investigators conducting research involving human subjects must standardize data fields to comply with the requirements as contained in the Data Structure, Standard Operating Procedure (SOP 302-CPC).
2) Accrual data must be submitted to the Clinical Trial Data Manager according to the procedures described in the Submission of Required Accrual Data, Standard Operating Procedure (SOP 303-CPC) or electronically as described in Web-Based Accrual Data Submission Procedures (SOP 306-CPC).
3) The Clinical Trial Data Manager is required to merge the data and create a report as specified in the Accrual Data Merge and Analysis, Standard Operating Procedure (SOP 304-CPC).
4) The Clinical Trial Data Manager is required to submit accrual data to the UACC Clinical Trials Office as specified in the Reporting Accrual Data to the UACC Clinical Research Shared Service, Standard Operating Procedure (SOP 305-CPC).
Investigators standardize required data fields
SOP 302-CPC

Data submitted by study staff to Clinical Trials Data Manager
SOP 303-CPC or SOP 306-CPC

Clinical Trials Data Manager merges data and generates report
SOP 304-CPC

Clinical Trials Administrator and Data Manager submits data and reports to Clinical Research Shared Services, Clinical Trials Office
SOP 305-CPC