

<u>Goal as stated in Quality Policy</u>	<u>WH-CSPCC Quality Objective</u>
STUDY DESIGN	In any calendar year, submitted protocols will not reflect a third (or higher iteration) CSSEC submission.
	In any calendar year, score of all CSSEC reviews are <=22 (if we have submissions)
	Actively recruiting studies are meeting 75% enrollment target within the previous calendar year. <i>Note: 75% enrollment target goal is for after at least 1 year of enrollment</i>
DATA INTEGRITY / QUALITY	100% of local IRs reviewed/accepted/assigned by QMS within 30 calendar days after entered.
	Lost to follow-up for primary outcome does not exceed 25% of the estimate used in the study design.
	During first year of study recruitment: Less than 10% of participants had a randomization in error. During subsequent years of study recruitment: Less than 1% of participants had a randomization in error.
	90% of queries, related to eligibility criteria elements and primary outcomes, were closed within 60 days, for randomized participants.
HUMAN SUBJECTS PROTECTION	<3% Informed Consent Forms for randomized participants with critical finding as described below within the previous calendar year. <i>Note 1: A critical ICF finding for randomized participant consents meeting any one of the following: Missing signature(s), missing dates, incorrect version of the ICF, consent not signed prior to start of study procedures, or ICFs missing (site does not have it).</i> <i>Note 2: The calculation is as follows: # of consent forms with at least one critical finding / # of consent forms expected for the calendar year (randomized participants only).</i>
	<3% of SAEs reported late/total # of SAEs reported within the previous calendar year, using “date site became aware of SAE” to allocate to calendar year.
	<3% of randomized participants with Eligibility Errors reported on protocol deviation forms within the previous calendar year. <i>Note: These are the site-confirmed cases with eligibility errors.</i>
IMPACT <small>*note time lag of approximately 1-2 years before citations to a primary publication may start appearing</small>	Maintain or exceed the number of previous year’s citations from CSP funded primary publications published in past 5 years.
	WH-CSPCC primary publications, published during the previous calendar year, were published in a journal with an impact factor of >=8 at the time of publication.