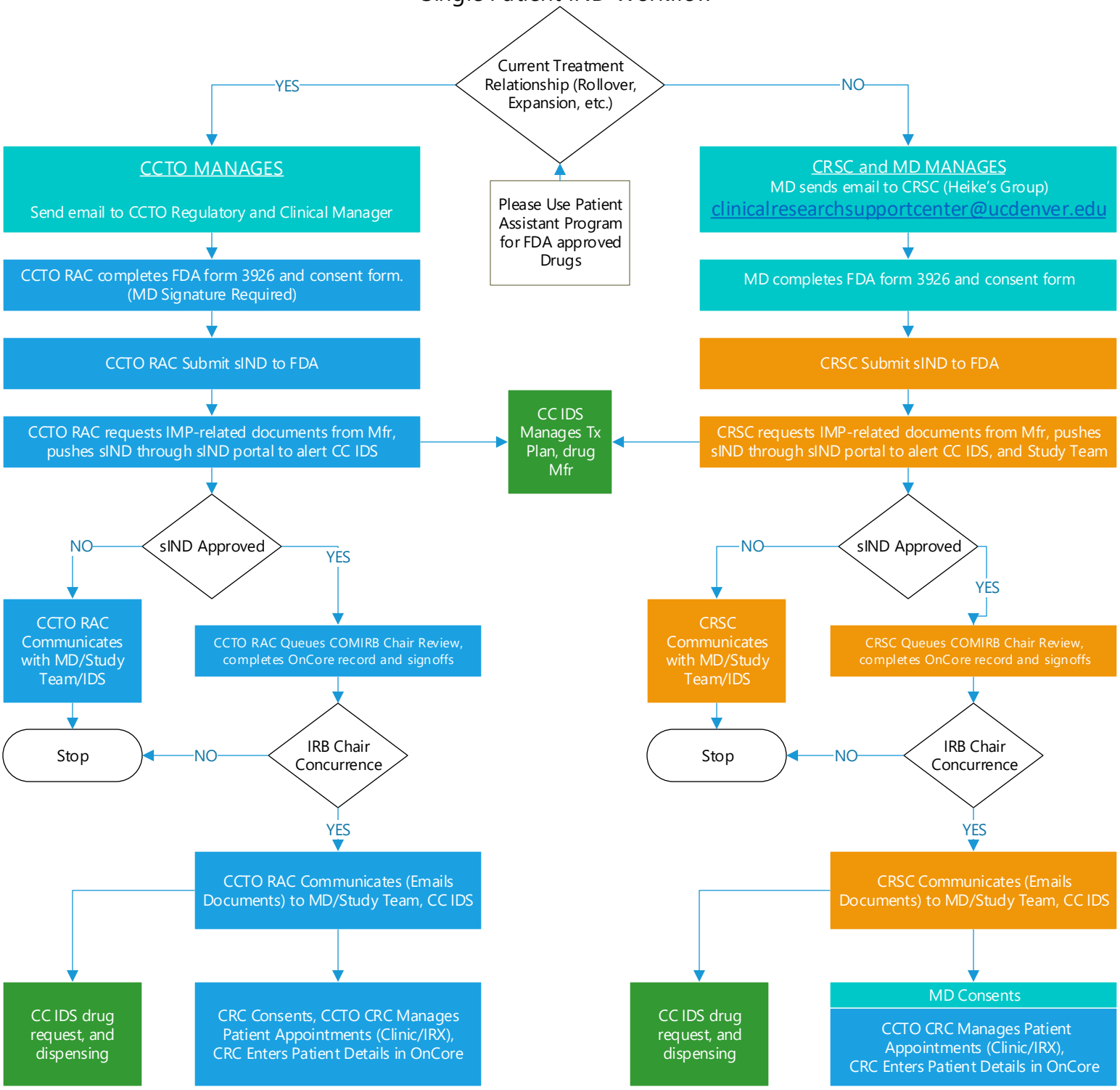
University of Colorado Cancer Center

Single Patient IND Workflow



SAE occurs – Clinical Team completes SAE paperwork w/MD input.
CCTO RAC submits to FDA and COMIRB as applicable
Annual Report – w/MD input CCTO RAC completes, submits to FDA
IRB Continuing review – CCTO RAC submits to COMIRB
IND withdrawal -– w/MD input CCTO RAC completes and submits

SAE occurs – MD completes SAE paperwork. CRSC submits to FDA and COMIRB as applicable, MD submits to Mfr
Annual Report– MD completes, CRSC submits
IRB Continuing review – CRSC submits to COMIRB
IND withdrawal – MD completes, CRSC submits

Orange – Clinical Research Support Center
Blue – Cancer Clinical Trials Office
Green – Cancer Center Investigational Drug Service (Pharmacy)
Teal – Clinician/ Medical Degree

spIND – Single Patient Investigational New Drug
CRSC – Clinical Research Support Center
CCTO – Cancer Clinical Trials Office
CC IDS – Cancer Center Investigational Drug Service (Pharmacy)

Communication should include COMIRB #, Protocol#, and appropriate documents ie: approved consents, patient material as applicable

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