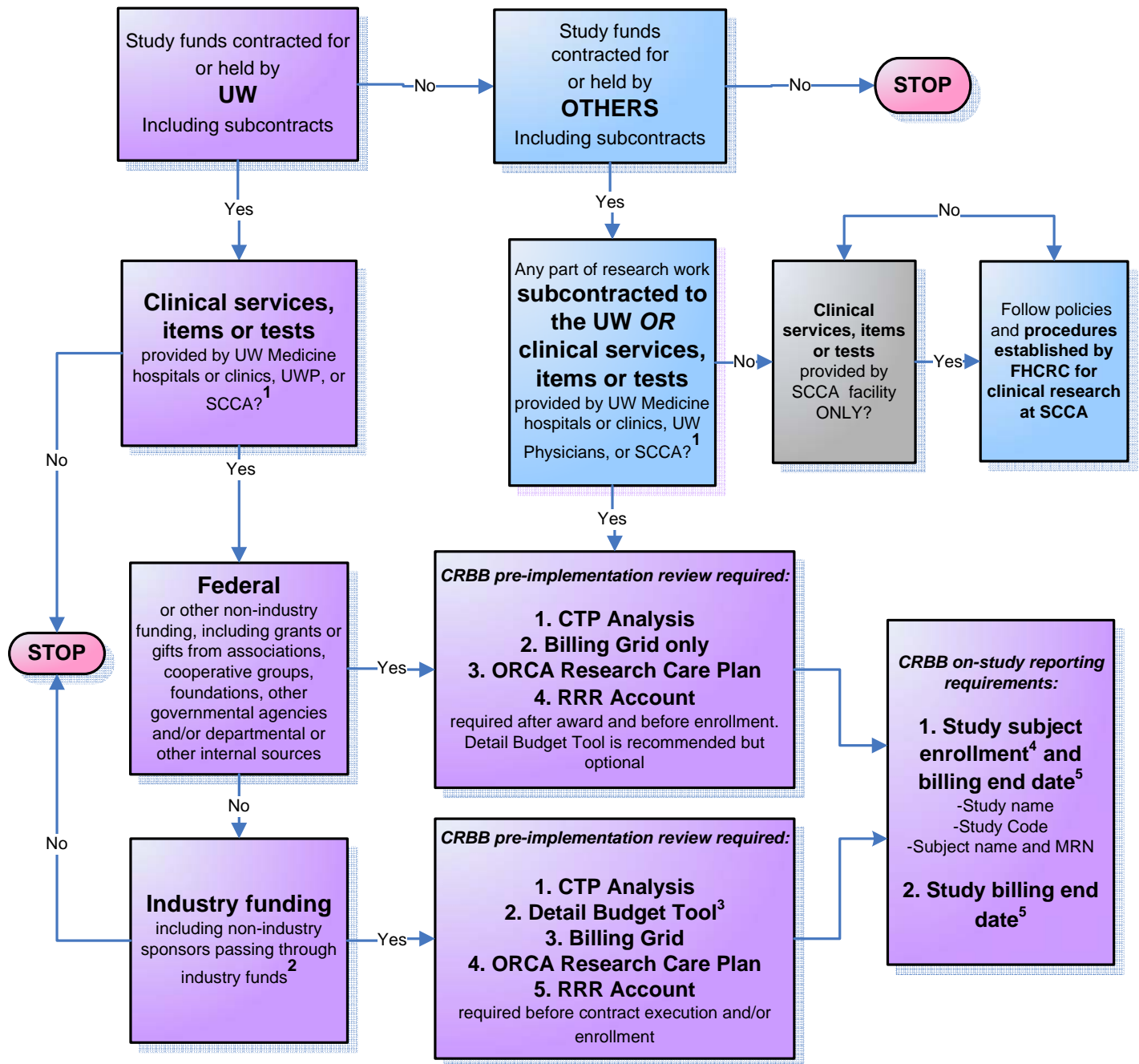


UW Medicine Clinical Research Budget & Billing (CRBB)
Clinical Trials Policy Review and Reporting Requirements

Revised July, 2010



1 – Includes: UW Medical Center, Harborview Medical Center, Eastside Specialty Center, Hall Health Primary Care Center and Sports Medicine Clinic. Also includes services, items or tests provided by Investigational Drug Services (IDS), Research Testing Services (RTS), the General Clinical Research Center (GCRC), and other research-only service areas such as the Diagnostic Imaging Service Center (DISC), MRI at South Lake Union and other dedicated research scanners. Studies using only RTS and DISC-type research-only services usually receive a CRBB waiver after initial review and may not require a Detail Budget Tool or RRR Account.

2 – Contact CRBB for further information.

3 – A Detail Budget Tool should be completed before initiating budget negotiation with sponsors.

4 – “Enrollment” means subjects who have consented and met screening criteria to participate in study protocol.

Studies using **only** RTS and/or DISC-type research-only services usually are exempt from study subject enrollment reporting requirements. Studies using IDS and GCRC are required to report subject enrollment. Contact CRBB for further information.

Studies requiring subject entry into the FHCRC Patient Accrual Tracking System (PATS) are reported to CRBB via PATS and are exempt from these subject reporting requirements. See <https://depts.washington.edu/crbb/SubjEnroll.shtml>

5 – Subject and study billing end occurs when one or all study participants are no longer receiving protocol-related patient care items, services or tests. See <https://depts.washington.edu/crbb/Closeout.shtml>