

Billing Compliance in Clinical Research CLINICAL RESEARCH BUDGETING AND BILLING (CRBB) REVIEW AND REPORTING REQUIREMENTS

TYPE OF STUDY		STUDY SERVICES	CRBB PRE-APPROVAL REVIEW REQUIREMENTS - STUDY TEAM					POST-APPROVAL REQUIREMENTS					
								STUDY TEAM		CRBB and/or UW PHYSICIANS			
Holder of Funds (including subcontracts)	Funding Source(s)	Services, items or tests ¹ provided by a practitioner who bills through UW Physicians, or an entity that bills through UW Medicine Patient Financial Services and/or CRBB ²	Coverage Analysis Checklist	ORCA Research Care Plan (ORCP) ³	Signed UW Medicine Billing Grid including Faculty Effort ⁴	Study Budget	Study Team Research Billing Training	Associate Participants in Epic and Report Participant Statuses and Active Billing Start and End Dates ⁴	Report Study-Related Inpatient Admissions ⁴	Assign CRBB #	Establish Epic "RRR" Study Account and Code	Set Billing Alerts in Epic	Bill Research Study & Apply Research Patient Care Rate Agreement (RPCRA)
UW	Industry or Combination	N								.			
		Y
	Non-industry	N								.			
		Y
Non-UW	Any	N								.			
		Y

¹ Includes facility or professional fees that are for:
 (A) Medically reasonable items or services that would be provided absent a clinical trial (for example, conventional or "usual care");
 (B) Provision of the investigational item or service, clinically appropriate monitoring of the effects of the investigational item or service and reasonable and necessary care arising from the provision of the investigational item, including complications ("expanded coverage");
 (C) The investigational item or service itself ("investigational"); *and*
 (D) Items and services provided solely to satisfy data collection and analysis or provided free or charge ("non-covered research only").

² See 202.G1 Billing By Site of Practice: http://depts.washington.edu/comply/docs/202_G1.pdf.

³ Study team must ensure a Research Care Plan (RCP) is entered into all enrolled participants' ORCA electronic medical records. The requirement may be waived for studies that meet exemption criteria. See https://depts.washington.edu/crbb/docs/ORCA_ResearchCarePlanDecisionTree.pdf.

⁴ Unless otherwise directed by CRBB.

⁵ When neither the study's funding nor Principal Investigator or key personnel are UW and when the study will utilize services only from research-only centers, a Purchased Services Agreement with the cost center may be required. For research-only centers, see 202.G1 Billing By Site of Practice: http://depts.washington.edu/comply/docs/202_G1.pdf.