

## Billing Compliance in Clinical Research

Policy Number: 01

First Effective Date: April 25, 2005

Revised: November 1, 2006, and May 1, 2008

### **Purpose and Scope**

The purpose of this policy is to clarify compliance requirements governing research studies contracted through the University of Washington when they include clinical services, items or tests that are provided by University of Washington Physicians (UWP), Seattle Cancer Care Alliance (SCCA), or UW Medicine hospitals or clinics, including UW Medical Center, Harborview Medical Center, Eastside Specialty Center, Hall Health Primary Care Center, and Sports Medicine Clinic.

### **Introduction**

The rules of federal and private payors govern the conditions under which clinical services, items and tests associated with a research study can be billed to study subjects or their insurers. The complexity of the rules and established procedures require that UW Medicine investigators, administrators, and staff work collaboratively with study sites and the practice plans to ensure that costs associated with clinical studies are billed in compliance with relevant laws and regulations.

### **Policy Statements**

1. All clinical services, items or tests billed to study sponsors, study subjects, and/or study subjects' Medicare, Medicaid, or other third party payers must be:
  - consistent with applicable billing rules of the third party payer being billed,
  - consistent with any grant provisions or contractual obligations entered into by UW Medicine or study sites,
  - represented consistently across all study related documents, including the protocol, grant, contract, budget, billing plan and informed consent document, and
  - consistent with UW Medicine procedures that establish safeguards to prevent billing mistakes.
2. Costs to the study subject or subject's third party payor associated with participating in the research study will be clearly disclosed in the Informed Consent Document signed by the study subject.
3. Each research study that includes clinical services, items or tests provided by UWP, SCCA, or UW Medicine hospitals or clinics will be reviewed by the Clinical Research Budget and

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Billing support office (CRBB) in advance of initiating the study. (See Appendix 1. CRBB Clinical Trials Policy Review and Reporting Requirements.)

4. Each research study that includes clinical services, items or tests provided by UWP, SCCA or UW Medicine hospitals or clinics will be conducted pursuant to a documented billing plan that serves as a guide for appropriately directing and coding charges to the study account, the study subject or a third party payor.
5. Each study subject who participates in a clinical research study that includes clinical services, items or tests provided by UWP, SCCA, or UW Medicine hospitals or clinics will be reported to the CRBB and registered as a patient of the UW Medicine hospital and/or clinic under the procedures applicable at each site.

## **Roles and Responsibilities**

### **General Responsibilities**

All **UW Medicine faculty, staff and trainees** are individually responsible for understanding and adhering to UW Medicine's policies and procedures, participating in required training, fulfilling recordkeeping requirements, reporting compliance concerns, seeking clarification when questions arise and responding in a timely manner to requests for information associated with internal audits or investigations.

Persons in **management or supervisory positions** have additional responsibilities, including communication of compliance and operational expectations, ensuring that appropriate training is taken, implementing and enforcing policies, and monitoring compliance.

For persons in **executive leadership positions** the **CEO, UW Medicine and Executive Vice President for Medical Affairs** has delegated additional specific authorities as follows:

- The **Associate Vice President for Compliance (AVPC)** develops UW Medicine-wide policies, establishes roles and responsibilities, participates in the education of faculty and staff, oversees the audit program, and coordinates the investigation and resolution of alleged noncompliance.
- The **CFO, UW Medicine and Vice President for Medical Affairs** oversees the development and implementation of process improvement projects, convenes related oversight committees, and facilitates the commitment of institutional resources that may be necessary to satisfy compliance and operational priorities.
- The **COO, UW Medicine and Vice President for Medical Affairs** leads process improvement teams, provides leadership and oversight for revenue cycle activities (e.g., registration, admitting, coding, hospital charge capture, clinical operations and patient financial services), and participates in the identification of tools and resources needed to implement compliance policies throughout the clinical enterprise.
- The **Vice Dean for Research and Graduate Education (VD-RGE)** leads process improvement teams, provides leadership and oversight for the CRBB, and serves as the School of Medicine (SOM) liaison with UW research offices to ensure effective coordination of shared concerns.

- The **Vice Dean for Clinical Affairs (VD-CA)** serves as chief medical advisor to the CRBB for resolving issues related to routine vs. experimental care, participates in study coverage analyses as needed and participates in the identification of tools and resources necessary to help ensure compliance with established policies and procedures.
- The **Vice Dean for Administration and Finance (VDAF)** works closely with the AVPC to establish and communicate the compliance and operational expectations for SOM chairs and administrators.
- **Compliance Officers** at the medical centers, SOM and practice plans work closely with the CRBB, study sites and operational departments to develop procedural safeguards; receive and investigate allegations of noncompliance; conduct audits; and participate in the development and delivery of compliance training.

## Operational Responsibilities

The **Principal Investigator (PI)** has primary accountability for all aspects of the clinical research projects operating under his/her name. Specific responsibilities include the following:

- Work closely with the study team and appropriate individuals<sup>1</sup> throughout the conduct of the study in order to ensure compliance with applicable billing rules as required by policy statement #1.
- Submit to CRBB for review each clinical research project that includes clinical services, items or tests provided by University of Washington Physicians, Seattle Cancer Care Alliance, or UW Medicine hospitals or clinics in advance of initiating the study using procedures established by the CRBB.
- Using procedures established by CRBB, register each study subject enrolled in any study that includes clinical services, items or tests provided by University of Washington Physicians, Seattle Cancer Care Alliance, or UW Medicine hospitals or clinics and notify CRBB when study subjects complete study participation.
- Perform a CTP coverage analysis based on the CMS National Coverage Decision for Clinical Trials Policy of 2007 in accordance with departmental and SOM procedures.
- Develop and maintain a budget (if required) and billing plan using tools and procedures established by the CRBB. (See Appendix 1. CRBB Clinical Trials Review and Reporting Requirements.)
- Ensure that services for study subjects enrolled in research studies are billed in accordance with the billing plan and adhere to the billing requirements of the CTP (e.g., coverage of routine costs in clinical trials and Category A and B investigational device billing rules).
- Report billing questions and concerns to billing staff for review and/or correction.
- Follow related clinical research implementation and billing procedures specific to each practice plan and study site.
- Conduct periodic reconciliation of charges to the billing plan.

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<sup>1</sup> A wide range of individuals may need to be involved throughout the conduct of the study, including but not limited to departmental administrators; budget and billing specialists in the CRBB, the practice plans or the study sites; clinic managers; compliance officers at the research billing sites; and coding specialists.

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- Ensure that appropriate documentation exists in the medical record when Medicare coverage is allowed under the 2007 CTP. (e.g., trial name, sponsor name, sponsor assigned protocol number).
- Notify CRBB when all billing for research studies that include clinical services ends.
- Adhere to UW Medicine records retention requirements.  
(<http://www.washington.edu/admin/recmgt/uw.gs7.html>)

The **Clinical Research Budget and Billing office (CRBB)** (<http://www.uwmedicine.org/Research/ResearchBudgetBilling/>) provides centralized support for PIs and is responsible for the following:

- Establishing and maintaining procedures for clinical research budgeting and billing;
- Providing education and outreach regarding clinical research billing procedures;
- Providing technical assistance, advice, tools and resources to PIs, study coordinators, staff at study sites and department administrators regarding third party payor reimbursement, budget development and billing and CTP coverage analyses;
- Allocating study charges to research study accounts;
- Maintaining inventories of clinical research studies and study subjects reported by research study teams
- Reporting unresolved billing concerns to appropriate compliance offices.

**Study site personnel** (including patient service representatives, billers, coders, clinic administrators and service providers) are responsible for working with the Principal Investigator and study team to ensure that services for patients enrolled in research studies are scheduled, coded, billed and recorded in accordance with the billing plan, seeking clarification when questions arise.

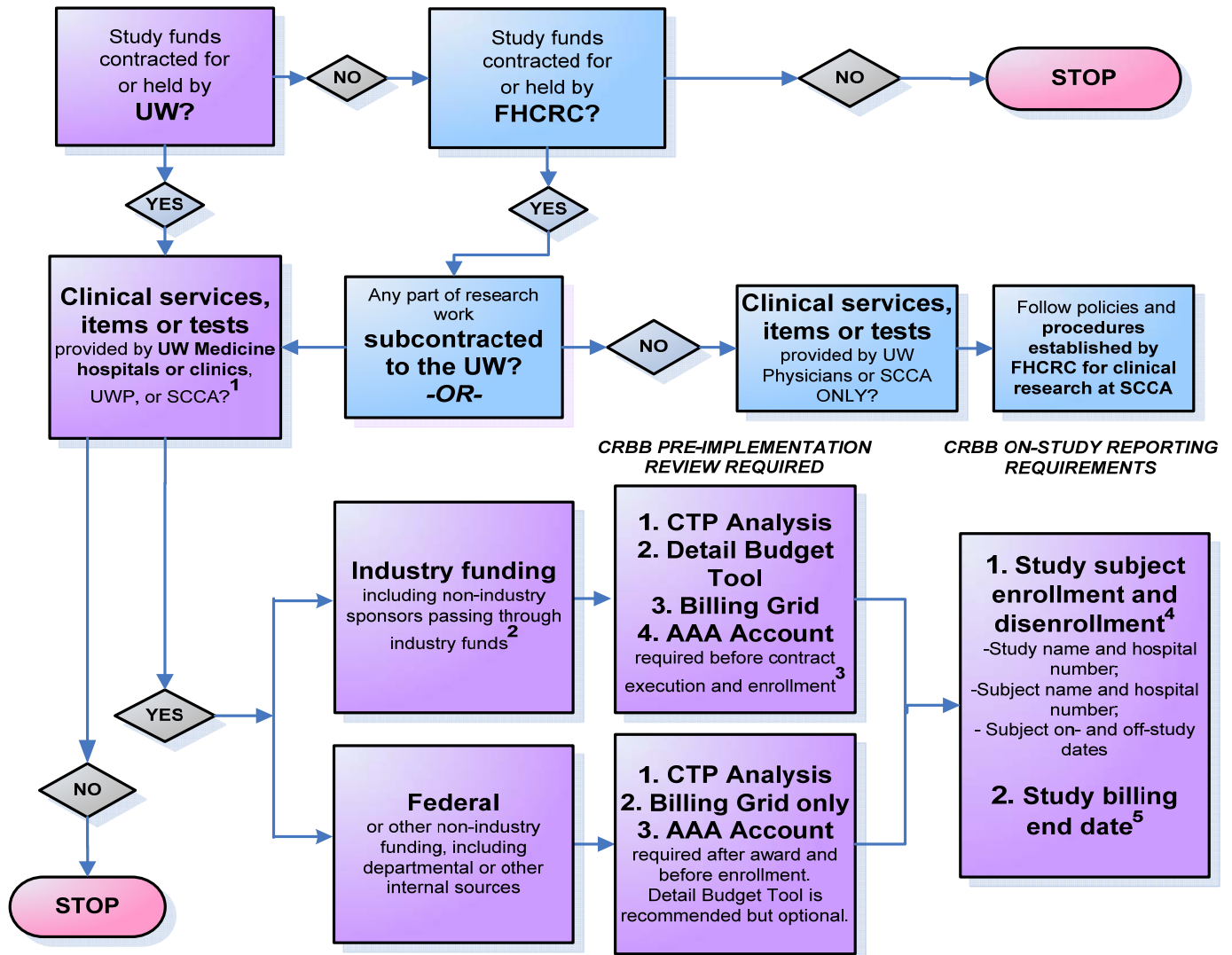
**Offices that bill facility and professional fees** are responsible for establishing business practices and systems that support compliance with research billing policies and procedures.

## Contacts and Resources:

UW Resource	Contact Number
UW Human Subjects Division	206-543-0098
Clinical Trials Budgeting & Billing Office (CRBB)	206-598-9490
SOM Compliance	206-616-4477
UW Medicine Compliance	206-543-3098
UWMC Compliance	206-598-2765
HMC Compliance	206-744-9006
UW Physicians Compliance	206-543-6420

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

Revised April, 2008



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 AAA Account.

2 – Contact CRBB for further information.

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

4 – Studies using **only** RTS and/or DISC-type research-only services 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 **not** exempt from these subject reporting requirements.

5 - See <https://staff.washington.edu/dorsee/toolkit.shtml#Subject> and <https://staff.washington.edu/dorsee/toolkit.shtml#Closeout>

