Applicability: UW Medicine

Policy Title: Budgeting and Billing Requirements for Clinical Research Using UW Medicine Faculty, Facilities or Services

Policy Number: COMP.202

Superseded Policies: Policy 1: Budgeting and Billing Requirements for Clinical Research Using UW Medicine Faculty, Facilities or Services
Policy 3: Clinical Research Subject and Study Reporting Requirements

Date Established: April 25, 2005

Date Effective: June 1, 2015

Next Review Date: June 1, 2018

PURPOSE
The purpose of this policy is to identify when clinical research studies require pre-implementation review by the School of Medicine Clinical Research Budget and Billing office (CRBB), and to establish standards for accurate budgeting and billing related to services that accompany clinical research.

This policy applies to the following:

- All clinical research utilizing the services of a member of UW Physicians (UWP), regardless of the site of practice;
- All clinical research studies that involve services, items or tests provided by a facility that bills through UW Medicine Patient Financial Services (PFS), or CRBB, whether the services are billed to study subjects, study budgets or both. See 202.G1 Billing Entity by Site of Practice.

DEFINITIONS
See UW Medicine Compliance Glossary.

POLICY
Complex federal and private payer rules govern the conditions under which clinical services, items and tests associated with a research study can be billed to study sponsors, study subjects and/or their insurers. Accurate research billing depends on planning and collaboration between the study team and a wide variety of individuals and offices before, during and after the study is initiated. For purposes of this policy, individuals who are billed for services associated with a research study are patients or participants in research studies, and are generically referred to as “study subjects.”
For all clinical research studies covered by this policy as described in the PURPOSE section:

1. Each clinical research study must be:
   a. Conducted pursuant to the study’s Medicare coverage analysis and approved billing grid that serve as guides for appropriately directing and coding charges to the study account, the study subject, or the subject’s third party payer; and
   b. Reviewed by CRBB to approve the coverage analysis and billing grid in advance of opening the study to subject accrual.

2. For industry-funded research projects contracted through the UW, a study budget must also be submitted to CRBB, reviewed, negotiated and approved prior to execution of the research contract.

3. Clinical services, items or tests billed to study sponsors, study subjects, and/or study subjects’ third party payer must be fully documented in the medical record. These services must be consistent with:
   a. Applicable billing rules of the third party payer that is billed;
   b. UW Medicine procedures that establish safeguards to prevent billing errors; and
   c. Any grant provisions or contractual obligations entered into by UW Medicine or study sites.

4. Potential costs to the study subject or subject’s third party payer associated with participating in the research study must be:
   a. Clearly disclosed and agreed to by the study subject; and
   b. Represented consistently across all study-related documents, including the protocol, grant, contract, budget, billing grid and Informed Consent Form.

5. All study subjects must:
   a. Be registered as patients of every UW Medicine hospital and/or site where study services will be delivered, under the procedures applicable at each site;
   b. Have appropriate information about their research participation documented in their medical record in accordance with the policies of the study site;
   c. Have their initial study enrollment and subsequent enrollment status changes reported within one business day, using the tools and procedures established by the UW School of Medicine/CRBB. Specific reporting methods and/or additional requirements may be established by the clinical sites of practice where the study is conducted.
   d. Have every UW Medical Center, Harborview Medical Center and Seattle Cancer Care Alliance Emergency Department (ED) or inpatient admission reported to CRBB when the encounter may include study-related clinical services, items or tests, unless otherwise directed. Study-related hospital inpatient admissions and ED visits must be reported within one business day of the subject’s admission.
6. CRBB must be informed when all study subjects have received all services in the study billing grid and study billing has ended.

REGULATORY/LEGISLATION/REFERENCES

PROCEDURE ADDENDUM(s) REFERENCES/LINKS
- UW Medicine Compliance Glossary.
- 202.G1 Billing Entity by Site of Practice

Contacts and Resources
Clinical Research Budget & Billing (CRBB):
Main Office: 206.543.7774, crbb@uw.edu
Billing Phone: 206.543.9006, crbills@uw.edu
https://depts.washington.edu/crbb/index.shtml
School of Medicine Compliance 206.685.0173
UW Human Subjects Division 206.543.0098
UW Medicine Compliance:
Main Office: 206.543.3098, comply@uw.edu
Toll-free line: 855.211.6193
Anonymous Compliance Hotline: 206.616.5248, 866.964.7744
UW Physicians Compliance 206.221.3345

ROLES AND RESPONSIBILITIES
Each UW Medicine faculty, staff and trainee is 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 audits or investigations.

- The Principal Investigator (PI) has primary accountability for all aspects of the clinical research projects operating under his/her name. The PI may delegate responsibility for the procedures required by this policy to appropriately qualified members of the study team.
• CRBB provides centralized support for PIs and is responsible for maintaining operations and researcher training programs to support proper budgeting and billing in clinical trials.

• Study-site personnel (including patient service representatives, billers, coders, clinic administrators and service providers) are responsible for maintaining procedures and working with the PI and study team to ensure that services for patients enrolled in research studies are scheduled, coded, billed and recorded in accordance with instructions from the study team, 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.

• Compliance officers in UW Medicine, the UW School of Medicine and the practice plans work closely with 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.

APPROVALS

UW Medicine Executive Compliance Committee  6/1/2015
Endorsed By  Date