

Applicability:	UW Medicine
Policy Title:	Budgeting and Billing Requirements for Clinical Research Using UW Medicine Faculty, Facilities or Services
Policy Number:	COMP.202
Date Established:	April 25, 2005
Date Effective:	February 19, 2021
Next Review Date:	February 19, 2024

PURPOSE

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

This policy applies to the following:

- All clinical research studies utilizing services, items or tests furnished by a provider who bills through UW Physicians, regardless of the site of practice;
- All clinical research studies (e.g., clinical trials and Medicare-approved registries) that involve services, items or tests provided by a facility that bills through UW Medicine Patient Financial Services (PFS) or CRBB-CTO, 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 services, items and tests associated with a clinical research study can be billed to study sponsors, study subjects and/or their insurers. Accurate clinical research billing depends on planning and collaboration between the study team and a wide variety of individuals and offices before, during and after the clinical research study is initiated. For purposes of this policy, individuals who receive billable services, items or tests associated with a clinical research study are considered to be patients who are clinical research study participants, 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 (performed and generated by the CRBB-CTO) that appropriately direct charges to the study account, the study subject, or the subject’s third party payer; *and*

- b. Reviewed by CRBB-CTO to approve the consistency of the study budget, as well as contractual and informed consent language with the coverage analysis and the billing grid in advance of opening the study to subject accrual.
2. For industry-funded research projects contracted through the University of Washington (UW), the final negotiated study budget must be submitted to CRBB-CTO prior to execution of the Clinical Trial Agreement (CTA, also called a “research contract”) to verify its alignment with the approved billing grid.
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 clinical 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, and such documents must not contain any language that indicates scenarios (including subject injury) in which Medicare, Tricare, or other federally funded health insurance programs will be charged first and the sponsor will pay the balance that the insurance does not cover. Such language violates federal law (e.g., Medicare Secondary Payer provisions) and can result in a False Claims suit against UW Medicine.
5. Study teams must ensure the following:
 - a. All study subjects are 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. All study subjects have appropriate information about their research participation documented in their medical record in accordance with the policies of the study site;
 - c. All study subjects have their initial study enrollment and subsequent enrollment status changes reported within one business day, using the tools and procedures established by CRBB-CTO. Specific reporting methods and/or additional requirements may be established by the clinical sites of practice where the study is conducted.
 - d. All research-related encounters, inpatient as well as outpatient, for enrolled study subjects are linked to the Epic study record. “Research-related encounters” are those called out as discrete time points in the study’s billing grid.
 - e. Study time point information must be documented in Epic for each research-related encounter in Epic. Alternatively, if study teams are unable to do so, they must provide such information to the research billing offices when requested. “Study time points” are those called out discretely in the study’s billing grid (e.g. Cycle 1 Day1). Study time point information is critical for CRBB-CTO to review charges for billing compliance.

6. Clinical research studies involving the use of an Investigational Device Exemption (IDE) device in which any study-related services, items or tests are billed to study subjects and/or study subjects' third party payers (i.e., the study sponsor is not covering 100% of these costs) must be reviewed and approved by the Centers for Medicare and Medicaid Services (CMS) and/or its designated Medicare Administrative Contractor (MAC), and the MAC must provide written confirmation that the study has been entered into its Medicare claims processing system. This review and approval process must be completed prior to CRBB-CTO activating the study's Epic Research Account and the commencement of study subject enrollment.
7. When a clinical research study ends (i.e., all study subjects have received all services in the study billing grid and study billing has ended), study teams must inform CRBB-CTO and complete other steps under the Study Billing Closeout Process.

REGULATORY/LEGISLATION/REFERENCES

- Centers for Medicare and Medicaid Services (CMS), Medicare Claims Processing Manual, CMS Pub. 100-04, Chap. 32 (Rev. 4237, February 8, 2019); available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c32.pdf>
- CMS, Medicare Benefit Policy Manual, Chapter 14 – Medical Devices (Rev. 198, November 6, 2014); available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c14.pdf>
- CMS, Medicare National Coverage Determinations (NCD) Manual Pub. 100-03, Transmittal 74: Medicare Clinical Trial Policy (CTP), (September 7, 2007); available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R74NCD.pdf>
- CMS, Coverage with Evidence Development; available at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>
- Social Security Act, Title 18, Section 1862 (42 United States Code Section 1395y): Exclusions from Coverage and Medicare as Secondary Payer; available at https://www.ssa.gov/OP_Home/ssact/title18/1862.htm
- US Department of Health & Human Services, Office for Human Research Protections, Federal Policy for the Protection of Human Subjects ('Common Rule'); available at <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>

PROCEDURE ADDENDUM(S) REFERENCES/LINKS

- [UW Medicine Compliance Glossary](#).
- [202.G1 Billing Entity by Site of Practice](#)
- UWMC, Medical Director Policies and Procedures: Medical Record
- HMC, Medical Staff Organization Bylaws, Rules and Regulations

Contacts and Resources

Clinical Research Budget & Billing (CRBB)/Clinical Trials Office (CTO):

Main Office: 206.543.7774, crbb@uw.edu; uwcto@uw.edu
 Billing Phone: 206.543.9006, crbills@uw.edu
<https://depts.washington.edu/crbb/>

UW Human Subjects Division

Main Office: 206.543.0098, hsdinfo@uw.edu
<https://www.washington.edu/research/hsd/>

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
<http://depts.washington.edu/comply/>

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.
- CTO and CRBB provide centralized support for PIs and are responsible for maintaining operations and researcher training programs to support proper budgeting and billing in clinical trials. This includes reviewing and advising on study budget development, as well as assisting in the development of Medicare coverage analysis compliant billing plans which help drive accurate billing to the right payer.
- 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.
- UW Medicine Compliance staff members work closely with CRBB-CTO, 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. UW Medicine Compliance also coordinates the required communications with the MAC in advance of IDE device clinical research study commencement, as described in #6 under the POLICY section.

APPROVALS

/s/ Beth DeLair
Beth DeLair
Chief Compliance Officer, UW Medicine
Associate VP for Medical Affairs, UW

3/15/2021
Date