UW Clinical Trials Office: Compliant Research Billing

Presented by Will Dean, Eli Reis, Laurel Weigler

10:40am-11:40am

UW Husky Union Building

Room 145

ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

UW CLINICAL TRIALS OFFICE: COMPLIANT RESEARCH BILLING

INTRODUCTION TO CLINICAL RESEARCH BOOT CAMP

WILL DEAN
ELI REIS
LAUREL WEIGLER
JULY 30, 2019

UW Medicine

SESSION TOPICS

What is the CTO?

What does this mean to your work?

The UW Medicine policies that support the compliant research billing

CTO CRBB – WHO WE ARE AND WHAT WE DO

CTO CRBB is a department within the UW School of Medicine created to support clinical research billing compliance through:

- ✓ Billing plans
- ✓ Sound budgeting
- ✓ Operational assistance
- ✓ Policy compliance

Why do we need a support offices like the CTO CRBB?

Is it really that complicated?

RESEARCH COMPLEXITY

- Clinical research itself is complex
- Federal regulatory requirements
- Medicare billing rules
- Multiple sponsors and funding scenarios sometimes have different rules for billing
- The university's decentralized institutional structure and multiple sites of practice
  - Diverse set of medical specialties & faculty investigators
  - Department-specific processes & procedures

SERVICES AND SUPPORT

Services we provide:

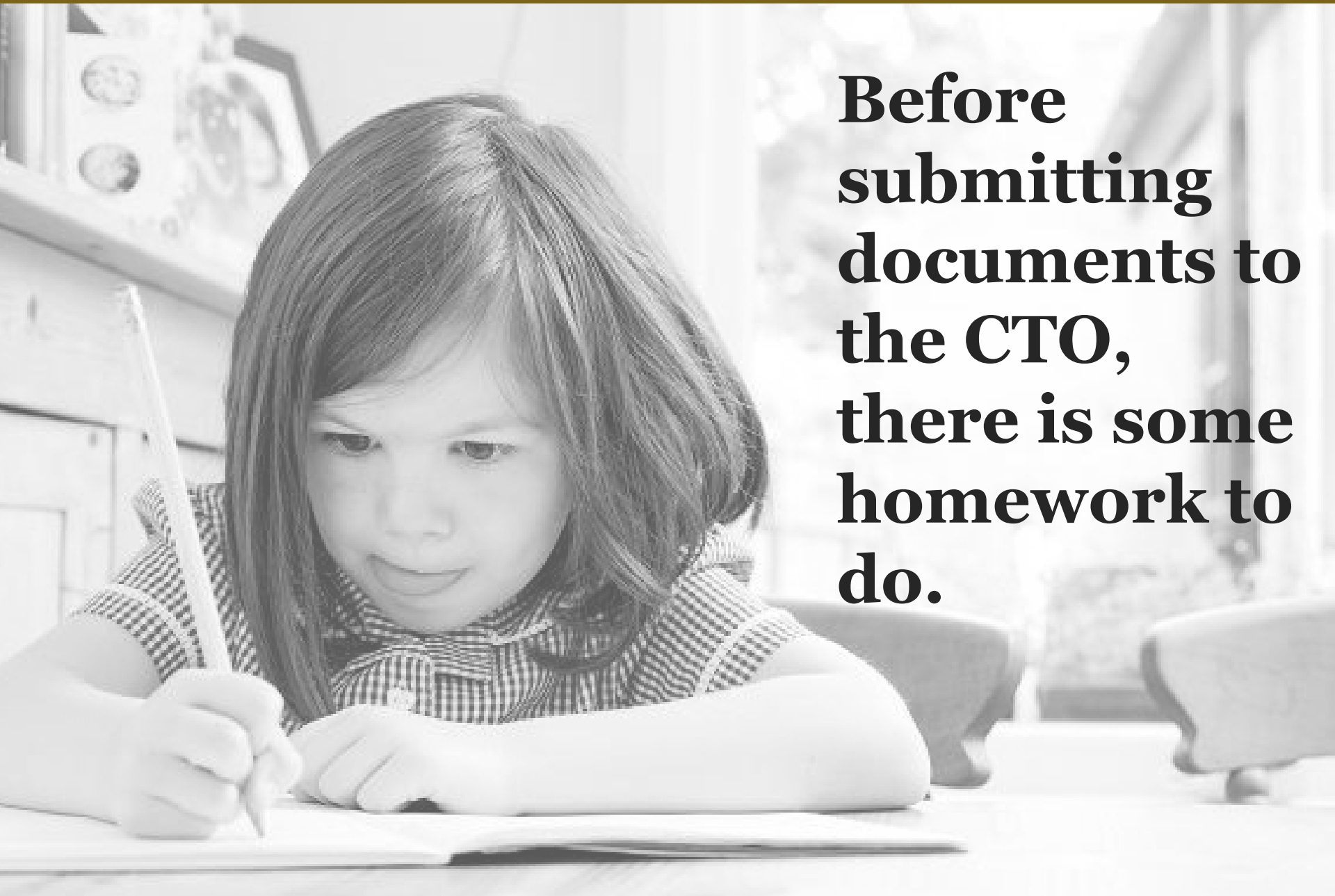
- Pricing for study-billable services, items, and tests
- Coverage analysis
- Billing grid production
- Budget development and negotiation
- Verify alignment among study documents
- UW clinical facility billing for research

SERVICES AND SUPPORT

Typical clinical research studies interact with the CTO throughout life of the study protocol.

- Pre-submission
- Submission
- Review
- Study Implementation
- Post Implementation
- Study Close Out

STUDY STAFF RESPONSIBILITIES: PRE-SUBMISSION



Before submitting documents to the CTO, there is some homework to do.

STUDY STAFF RESPONSIBILITIES: PRE-SUBMISSION

- ✓ Evaluate financial feasibility of conducting the study
- ✓ Evaluate the protocol to determine if the study involves any services, items, or tests that will bill to the patient
- ✓ Coordinate with service center managers for availability of services at specific locations
- ✓ Prepare submission documents
- ✓ Determine if you submit via email or through the Study Review and Management Portal (sRAMP)

If you answer 'yes' to any of these questions, you may need to submit via sRAMP.

- Will any study participants have study-related services, items or tests at SCCA Sites of Practice?
- Is this study cancer or cancer-related with study-related services, items or tests? (*Excludes Seattle Children's studies utilizing only CUMG Providers)*
- Is this study conducted by a Principal Investigator who is a Cancer Consortium Member with study-related services, items or tests at UWM Sites of Practice?

Submitting your study to the CTO involves submitting:

- Completed CRBB Intake form or sRAMP Parts 1-3,
- Protocol
- Draft informed consent form
- There may be additional documents, based on study specifics and review requirements

CTO RESPONSIBILITIES: SUBMISSION

Once the CTO receives your submission, we do a cursory evaluation for completion.

If all documents are included and complete, the study undergoes Coverage Analysis.

CTO RESPONSIBILITIES: SUBMISSION

The completed Coverage Analysis is the basis for Billing Grid.

- The CTO Research Coding team verifies codes and adds prices for research related procedures
- Coordinates with UW Radiology, Pathology, Lab Services and IDS, AKA "The Big Four," to determine the pricing for their services
- Returns completed pricing to study team

CTO RESPONSIBILITIES: REVIEW

During Review, CTO Budget Specialists review the study documents:

- For facility and professional services vs effort
- For document alignment

CTO RESPONSIBILITIES: IMPLEMENTATION

Once the CTO completes its review and the contracts have been signed, the CTO is responsible for:

- ✓ Creating the Epic Research Study Account
- ✓ Notifying study teams and relevant departments of the Epic Research Account creation

CTO RESPONSIBILITIES: POST IMPLEMENTATION

After your Epic Research Account is implemented, the CTO:

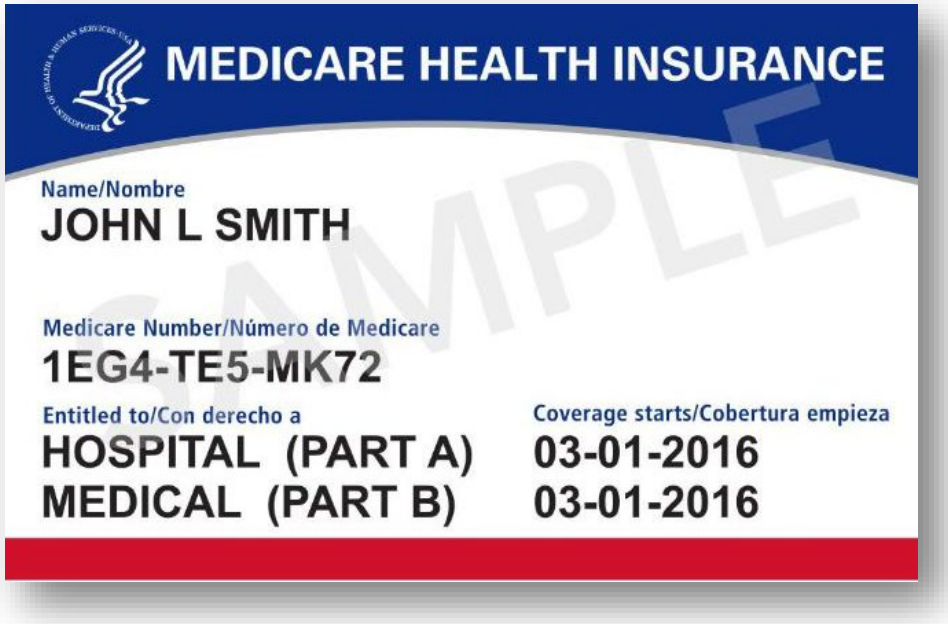
- Monitors subject enrollment status
- Offers support for the hospital charge submission process
- Invoices your study for UW hospital charges
- Assists with billing error resolution

We may not always have the answer to your specific billing questions, but we're a good starting point for finding the correct resource.

MEDICARE MOTIVATION

Many of the patients who participate in clinical research have Medicare as their health insurance.

Because of its complicated nature, and the possibility of expensive fines, Medicare's policies drive much of the University of Washington's methodology regarding billing for clinical research.



MEDICARE CLINICAL TRIAL HISTORY

- Pre-2000, Medicare did not cover care associated with clinical trials
- 2000 (updated 2007), Medicare National Coverage Decision (NCD) allowed coverage of some costs associated with Qualifying Clinical Trials (QCTs)
- 2003 (updated 2015), Medicare Prescription Drug, Improvement, and Modernization Act (MMA) allowed Medicare payment of the routine costs of care furnished to Medicare beneficiaries in certain categories of Investigational Device Exemption (IDE) studies

MEDICARE: HOW DOES A STUDY QUALIFY?

It fulfills 3 basic requirements for Medicare coverage

&

It possesses 7 desirable characteristics, or is assumed to have those characteristics, mostly because of its funding source

MEDICARE: HOW DOES A STUDY QUALIFY?

Must meet all three requirements

Evaluate an item or service that falls within a Medicare benefit category

Have therapeutic intent

Enroll patients with diagnosed disease

Must be at least one of these requirements

Funded by NIH, CDC, AHRQ, CMS, DOD or VA

Supported by center or cooperative group funded by NIH, CDC, AHRQ, CMS, DOD or VA

Conducted under an investigational new drug application (IND) reviewed by the FDA, DOD or VA

IND exempt under 21 CFR 312.2(b)(1)

MEDICARE: HOW DOES A DEVICE STUDY QUALIFY?

Investigational Device Studies have different criteria. A checklist and application instructions are available on the Center for Medicare and Medicaid Services (CMS) website at: https://www.cms.gov/Medicare/Coverage/IDE/Downloads/IDE-Study-Criteria-Crosswalk-Sep-2014.pdf

1. The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.
2. The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
3. The study results are not anticipated to unjustifiably duplicate existing knowledge.
4. The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.
5. The study is sponsored by an organization or individual capable of successfully completing the study.
6. The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812, and 45 CFR part 46.

MEDICARE: HOW DOES A DEVICE STUDY QUALIFY?

Continued…

7. Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studies is life threatening and the patient has no other viable treatment options.
8. The study is registered with the National Institutes of Health National Library of Medicine's ClinicalTrials.gov.
9. The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.
10. The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.

COVERAGE ANALYSIS

The CTO evaluates protocols to determine how services, items, and tests can be billed according to Medicare National and Local Coverage Determinations.

- Provides the foundation for the billing grid and resulting budget creation
- If your study has NO patient billables, you may elect to skip coverage analysis and create the billing grid on your own. If this describes your study, contact the CTO for more information.

Research billing is a priority for the Department of Justice (DOJ)

Sample of Research-related Settlements:

- 2005 Rush University ($1M)
- 2010 USC/Tenet Healthcare ($1.9M)
- 2013 Emory University ($1.5M)
- 2019 GenomeDX Biosciences Corp ($1.99M)

RESEARCH BILLING RISKS

Double-billing research services by accepting sponsor funding and billing patient (Medicare) for the same services.

Requires that we identify up front the appropriate payer for each service and budget accordingly.

RESEARCH BILLING RISKS

Billing non-covered research services to Medicare, or billing covered services incorrectly.

✓ Requires clear billing plan for each service (Billing Grid)

✓ Requires that charges are directed accurately **at the point of care**

RESEARCH BILLING RISKS

2005 Rush University - $1M
2010 USC/Tenet - $1.9M
2013 Emory - $1.5M
2019 GenomeDx Biosciences Corp - $1.99M

- Accepted funding from grant/contract and also billed Medicare, i.e., **double billing**
- Billed Medicare for services that were stated to be "free of charge" in ICF
- Received reimbursement for services that were not medically necessary
- Received reimbursement for services provided in the context of a non-QCT

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Clinical Research Policies

UW MEDICINE CLINICAL RESEARCH POLICIES

Budgeting and Billing Requirements for Clinical Research Using UW Medicine Faculty, Facilities or Services- COMP.202

- Established in 2015, Current Version Effective October, 2017
- Outlines operational and reporting requirements
    - When clinical research studies require pre-implementation review by the CTO
    - On-study and post-study research-related reporting requirements
    - Medical record documentation requirements

UW MEDICINE CLINICAL RESEARCH POLICIES

Which Studies Are Within Scope?

- All clinical research utilizing the services of a member of UW Physicians (UWP), at any site of practice
- All studies that involve services, items or tests provided by a facility that bills through the CTO or HMC/UWMC/NWH Patient Financial Services (PFS), whether the services are billed to study subjects, study budgets or both

UW MEDICINE CLINICAL RESEARCH POLICIES

Budgeting and Billing Requirements for Clinical Research Applies to Studies That Involve:

Services, items, or tests billed to a study

Services, items, or tests billed to a patient/third party payer as part of a QCT

...or studies that involve a combination of both patient and study billing.

POLICY STATEMENT #1

Each clinical research study must be conducted pursuant to the study's Medicare coverage analysis and an approved billing grid that serves as a guide for appropriately directing and coding charges to the study account, the study subject, or a third party payer…

Site(s) of Service		Clinical Service or Item Description	CPT (or EAP if needed when Billed to Research)	Cost Center (when Billed to Research)	P/E	S	I	Visit Short Title	SCRN D-56	SCRN D-28	SCRN D-14	C1D1	C1D8	C1D15	C2D1	C2D8	C2D15
								Visit Day #									
								Visit Window				+/- 1d	+/- 1d	+/- 1d	+/- 1d	+/- 1d	+/- 1d
								Week/Cycle →									
								Comments ↓									
Billed	UWMC/SCCA	HC FLUORODEOXYGLUCOSE F-18 FDG DX UP TO 45 MCI	A9552	96700				INV if done outside of SOC window ($)									
	UWMC/SCCA	B1&/JT IMG WHBDY	78306	99200	P	S		INV if done outside of SOC window ($)									
	UWMC/SCCA	HC TECHNETIUM TC-99M MEDRONATE DX UP TO 30 MCI	A9503	99200				INV if done outside of SOC window ($)									
	SCCA	HC FOB L4 ESTABLISHED OUTPT VISIT	99211-99215	72900, 73500, 73600, 75300, 75500, 75600, 97600	P			Any levels between II-V; Occur in Lung/Head/Neck, GI, GU, GynOnc, GenOnc, Breast or Melanoma/ Renal clinic; Includes PE, ECOG, Vitals & weight; INV if outside of SOC window at SCRN					1	1		1	1

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POLICY STATEMENT #1

…and be reviewed by the CTO **in advance** of opening the study to subject accrual.

POLICY STATEMENT #2

For industry-funded research contracted through the UW, a study budget which includes a billing grid must be submitted to the CTO and reviewed prior to the execution of the research contract.

POLICY STATEMENT #3

Clinical services, items or tests billed to study sponsors, study subjects, and/or study subjects' Medicare, Medicaid, or other third party payers must be fully documented in the medical record and be consistent with:

- applicable billing rules of the third party payer being billed
- UW Medicine procedures that establish safeguards to prevent billing errors and
- any grant provisions or contractual obligations entered into by UW Medicine or study sites

POLICY STATEMENT #4

Potential costs to the study subject or subject's third party payer associated with participating in the research study must be:

1. clearly disclosed in the Informed Consent Form (ICF) and signed by the study subject; and

2. represented consistently across all study related documents, including the protocol, grant, contract, budget, billing grid and ICF

POLICY STATEMENT #5

All study subjects must:

- 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;
- Have appropriate information about their research participation documented in their medical record in accordance with the policies of the study site

POLICY STATEMENT #5

All study subjects must:

- 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/CTO. Specific reporting methods and/or additional requirements may be established by the clinical sites of practice where the study is conducted.

POLICY STATEMENT #5

All study subjects must have every:

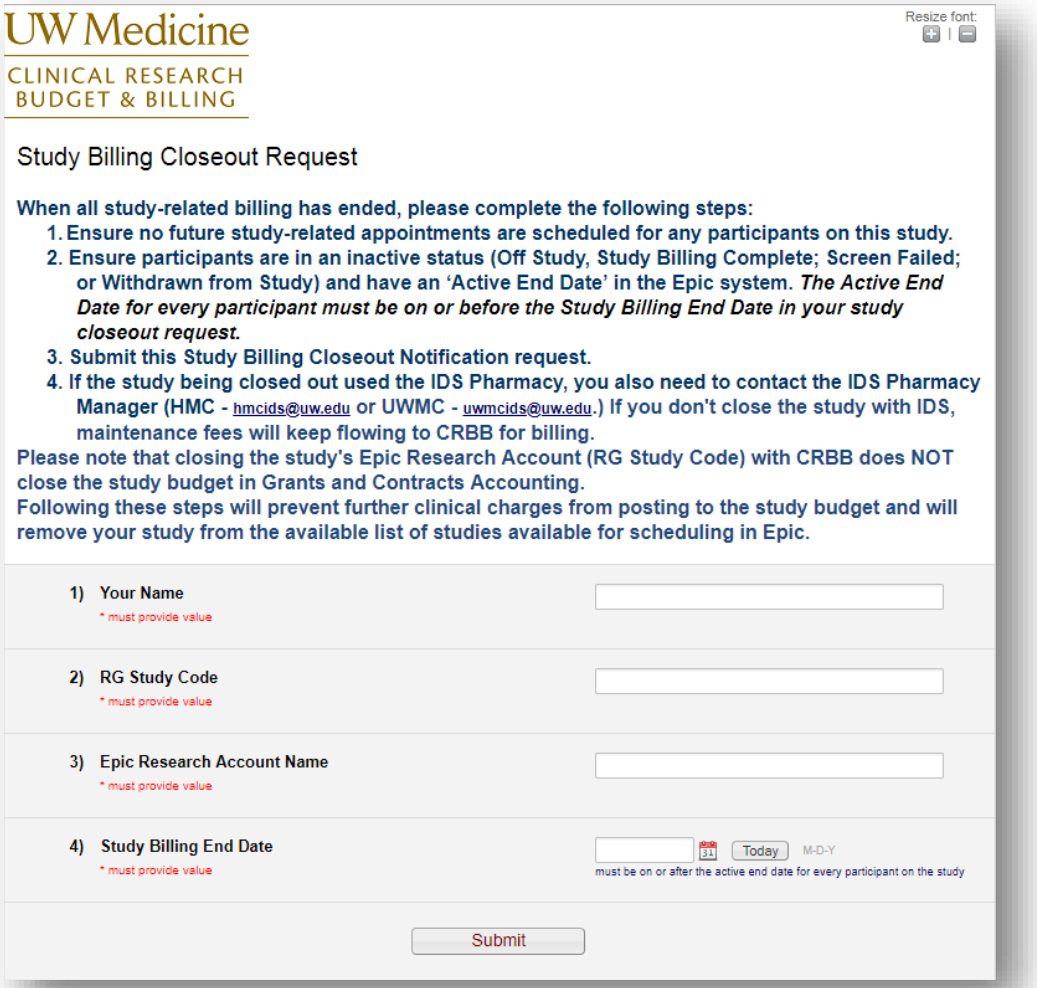
- UW Medical Center,
- Northwest Hospital,
- Harborview Medical Center and
- Seattle Cancer Care Alliance…

Emergency Department (ED) or inpatient admission reported to CTO 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.

POLICY STATEMENT #6

The CTO must be informed when all study subjects have received all services in the study billing grid and study billing has ended.

This is accomplished by completing the REDCap Study Billing Closeout Notification located on the CRBB website at:



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CLINICAL RESEARCH BUDGET & BILLING

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Study Billing Closeout Request

When all study-related billing has ended, please complete the following steps:

1. Ensure no future study-related appointments are scheduled for any participants on this study.
2. Ensure participants are in an inactive status (Off Study, Study Billing Complete; Screen Failed; or Withdrawn from Study) and have an 'Active End Date' in the Epic system. *The Active End Date for every participant must be on or before the Study Billing End Date in your study closeout request.*
3. Submit this Study Billing Closeout Notification request.
4. If the study being closed out used the IDS Pharmacy, you also need to contact the IDS Pharmacy Manager (HMC - hmcids@uw.edu or UWMC - uwmcids@uw.edu.) If you don't close the study with IDS, maintenance fees will keep flowing to CRBB for billing.

Please note that closing the study's Epic Research Account (RG Study Code) with CRBB does NOT close the study budget in Grants and Contracts Accounting.
Following these steps will prevent further clinical charges from posting to the study budget and will remove your study from the available list of studies available for scheduling in Epic.

1) Your Name
* must provide value

2) RG Study Code
* must provide value

3) Epic Research Account Name
* must provide value

4) Study Billing End Date
* must provide value
Today M-D-Y
must be on or after the active end date for every participant on the study

Submit

https://depts.washington.edu/crbb/Closeout.shtml

REPORTING TIMELINE SUMMARY

1. Clinical research subject enrollment status
   - Within one working day of status change
   - Via Epic or OnCore
2. Study-related inpatient or ED admissions
   - Within one working day of admission
   - Via Epic In Basket message
3. Research study account billing close-out
   - Within 45 days of final billing end
   - Via REDCap survey

UW School of Medicine

Clinical Research Faculty Effort Policy

FACULTY EFFORT POLICY

Established September 2009 to address professional services & faculty effort for clinical research studies

School of Medicine faculty must fully account for all their professional services in clinical research as either:

Effort on a grant or contract (i.e. budgeted salary) if they are the PI or 'key personnel' for the study

OR

Professional fees charged to a patient/third party, Epic Research Study Account, or recharge center

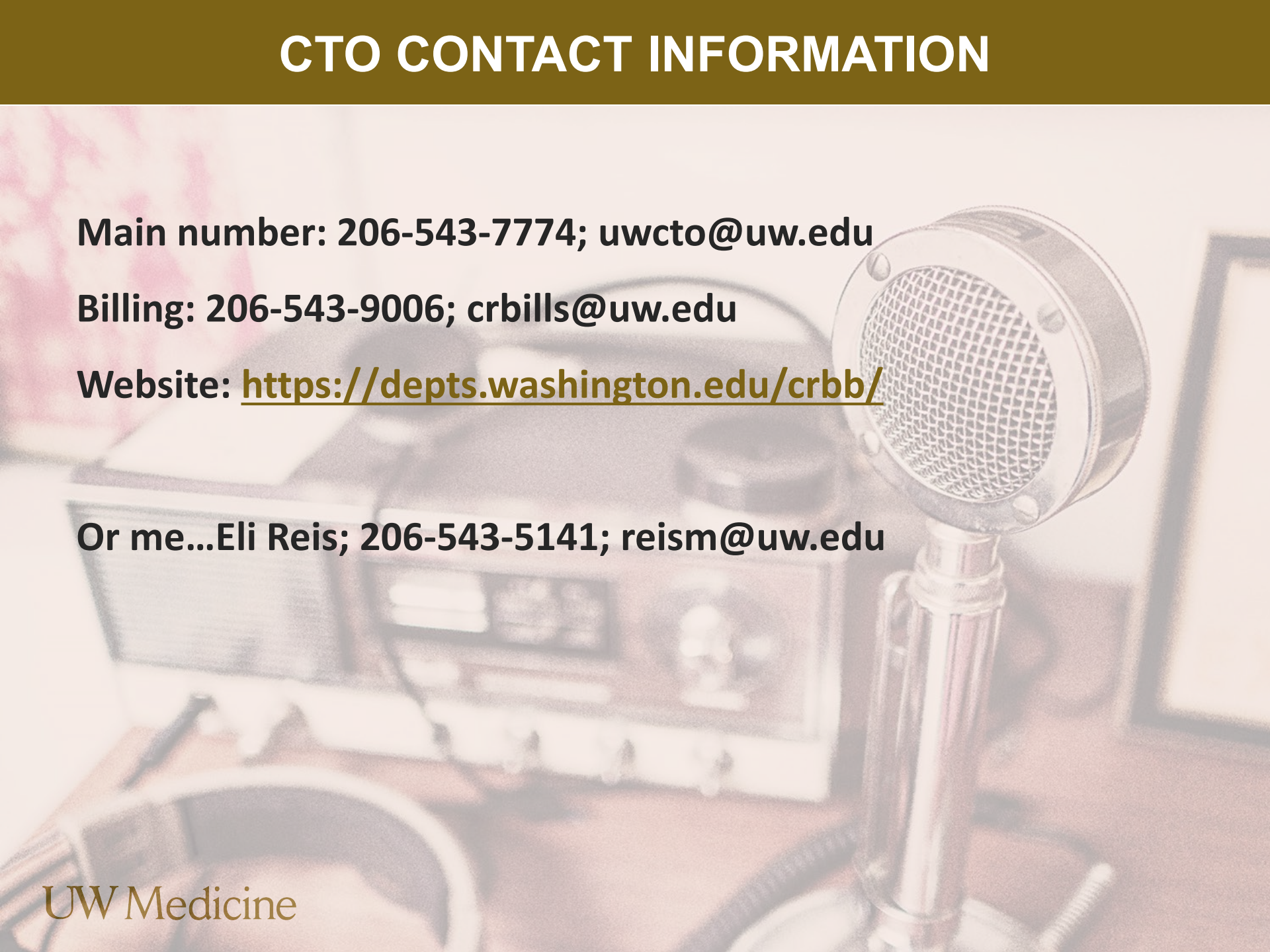
CTO CONTACT INFORMATION

Main number: 206-543-7774; uwcto@uw.edu

Billing: 206-543-9006; crbills@uw.edu

Website: https://depts.washington.edu/crbb/

Or me…Eli Reis; 206-543-5141; reism@uw.edu



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