Research Related Claims Management
What is This & Why is it Important?

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knowledge changing life

MEDICAL COLLEGE OF WISCONSIN

Objectives of Review Session

1. What is meant by Research Related Claims Management
2. Who is at risk for non-compliant Claims Management
3. CRC's or default study team members Role in Compliance
4. Understand steps of correction if error occurs

What Is Research Claims Management?

- Process by which MCW and Affiliated Hospitals (Froedtert/Children's) manage, or process research subject claims (charges) generated in EPIC due to completion of a research related procedure, visit, or use of space

- All research claims consist of a MCW (Professional Billing or PB) component and a Facility (Hospital Billing or HB) component
  - Processed separately by CPS (MCW) or OCRICC or DOP (FH or CW)
  - Timely in nature, expectation is study team submission within 24 hours

- Focus for this presentation is MCW or Professional Claims (Billing)

What Research Procedures Meet Criteria For Professional Billing (PB)?

- Any procedure or test not completed on a piece of equipment provided by the sponsor
- All encounters completed by a MCW provider
  - Includes MDs, NPs, PAs, or any person who generate a billable claim in EPIC
- If procedure occurred in a MCW Facility
- Any of the above procedures, space uses or services that post a billable line item (charge or PB claim) in EPIC!!!!!!!!!

Risks of Non-Compliant Claims Management

Study Subject

- Financial Risk
- Trust with Study Team

Who Else

- MCW
- Hospital Partner(s)
- Investigator
- CRC

Responsibility for Compliant Claims Management?

Primary Responsibility

- Medical College of Wisconsin
- Principal Investigator
- Research Coordinator

Supporting Partners

- OCRICC for Froedtert Hospital Billing or Children's Hospital Billing
- Clinician Physician Services (CPS, aka MCW Billing) for Professional Billing
- MCW Office of Research
- MCW Corporate Compliance

Research Claims Management Fact Check

Myth	Fact
The OCRICC Approval is the answer to all Claims Management	The OCRICC Approval only addresses Hospital Billing (HB); OCRICC reviews claims based on Pre-Trial Approved Coverage Analysis
There are No Professional Claim for the Study, they are All Hospital Claim	Every procedure or visit with a hospital charge has a professional component
CRC can submit Professional Claims when there is time	CPS processes Claims posted in EPIC within 24 hrs. & default is to Patient Insurance

Research Claims Management Across Enterprise

Froedtert Health

- For Hospital Billing Claims only
- OCRICC ONLY requires/wants notification of variances from Coverage Analysis (included with OCRICC Approval)

Children's Wisconsin

- For Hospital Billing Claims or P-TRU charges only
- No change in CW or P-TRU process

Medical College of Wisconsin

- Notification provided via the "Human Research Charge Notification" Qualtrics survey within 24 hours of encounter (visit) or procedure
- Applies to all research procedures, services or MCW space use occurring at Froedtert Health, Children's Wisconsin or Community Physicians (CP) locations

Quick Check-Is Your Protocol Compliant?

What does the Informed Consent Form(s) state regarding cost of study related procedures?

- Paid by Sponsor
- Paid by Subject Insurance

What does your Clinical Trials Agreement (CTA/contract) and Budget state?

- Paid by Sponsor
- Paid by Subject Insurance

What does you study Coverage Analysis (MCA) state?

- Paid by Sponsor
- Paid by Subject Insurance with Q modifiers attached (clinical or research service)

ARE PROFESSIONAL CLAIMS FOR ALL STUDIES YOU SUPPORT COMPLIANT?

Ready for that Corporate Compliance or Medicare Audit?

Process for Communicating and Survey Benefits

Submit PB claims using the "Human Research Charge Notification" Survey!

Found on train.mcw.edu

Benefits

- Standardized, automated tool for use across the enterprise
- HIPAA-compliant method of communication of participant information
  - ✓ Automatically triggered to programmed locations when submitted (CPS, OOR, CRC & Radiology)
- Provides CPS with required information for complaint claims processing
  - ✓ Fields represent what is seen/used to process research claims in Epic
  - ✓ Consider Qualtrics a Bridge & preparation for the MCW Financials Project
  - ✓ Validates that linking of visits & orders in EPIC is functioning appropriately for CPS
  - ✓ CPS does not have access to the Study Coverage Analysis
- Supports institutional compliance and volume oversight
  - ✓ Reporting capabilities for both CPS & MCW Corporate Compliance
- Affords standardized method for long-term documentation of compliance
  - ✓ Printable email to submitting CRC for inclusion in study billing records

When did the Need to Report Change Occur?

Always a Requirement

- First, the **need to report** professional research related claims appearing in EPIC, **IS NOT A CHANGE!!!!!!**

Issues Raised

- July 2020: CPS/MCW Billing & MCW Research Corporate Compliance noted that PB claims were not being managed well by research teams
- Findings: Research study team practices placed or places subjects, MCW & Investigators at risk
- October 2020: Implemented "Human Research Charge Notification" Qualtrics survey for research-related PB charge notifications, with requirement for submission within 24 hours of research-related visit or procedure

Communication Efforts

- Infoscope, Research Pulse, Research Ambassadors, HRPP Lunch & Learn
- CRCs attempting to use the "old method" of sending an email to CPS, were directly referred to Sue Mauermann for review of the new process & expectations
- Ongoing department level visits

Events To Include On Qualtrics Survey

Include

- **Each event!!!!** Coverage analysis completed prior to study initiation should be your guide
- Include each study visit, procedure, or service provided by an MCW provider (licensed MD, or other licensed practitioner (NP or PA) as a separate line item or event, regardless of who is paying (study or insurance)
- Accurately complete all fields related for each line item, each field represents information required for claims management in EPIC
- Form must be completed within 24 hours of study procedure/visit (best practice = first task after procedure/visit completion)

Do Not Include

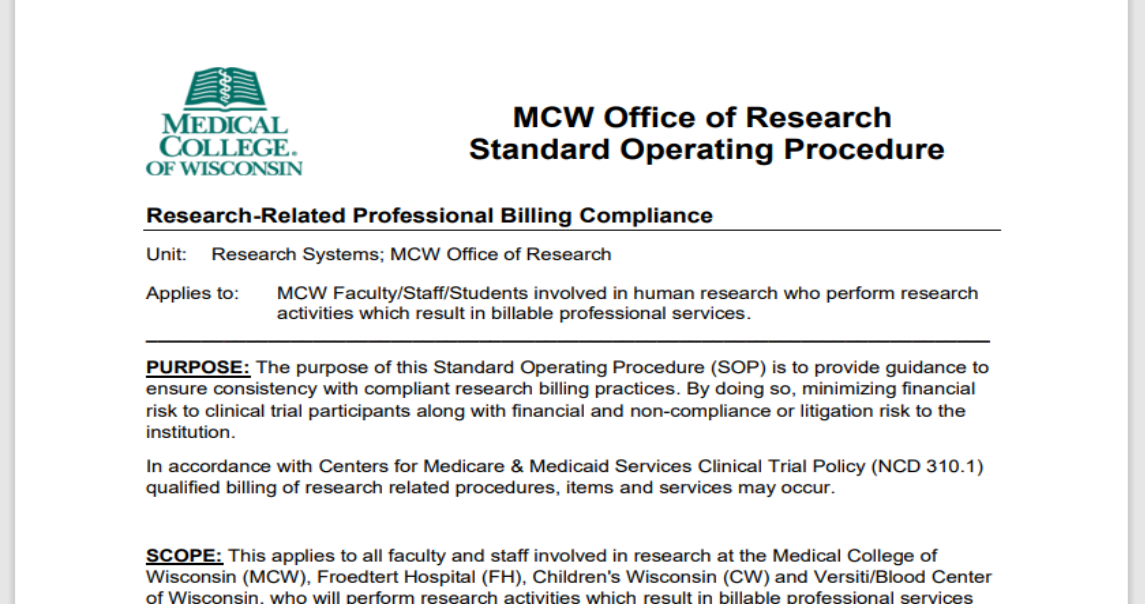
- Procedures or tests completed on sponsor supplied equipment or sent to study core labs, as these items would not generate a claim or charge to be processed by CPS in EPIC
- Study procedures completed by CRC or Study Nurse (Consent, QOL completion, AE assessments)
- Study procedures or visits completed in either A-TRU or P-TRU unless they generate a billable claim in EPIC

Information or Details for Qualtrics Survey

1. Study Coordinator information & department
   - CRC receives a bounce back email of Qualtrics for the study financial records
   - Option to enter second email address to support financial processes of study teams
2. Identifies the treating physician
   - Treating physician is provider responsible for that visit or procedure
3. Participant information
   - Name, MRN, DOB (identifies right person for claims management)
4. Study details
   - IND or IDE numbers, IRB identifiers, NCT number
5. Study diagnosis
   - Particularly important if Medicare is involved
   - Adverse event diagnosis
6. Each study procedure, image, visit, included is a drop-down for location identifying all potential clinic or hospital locations

Anything Else CRCs Should Know?

[Research Billing Resources (train.mcw.edu)]



MEDICAL COLLEGE OF WISCONSIN

MCW Office of Research
Standard Operating Procedure

Research-Related Professional Billing Compliance

Unit: Research Systems; MCW Office of Research

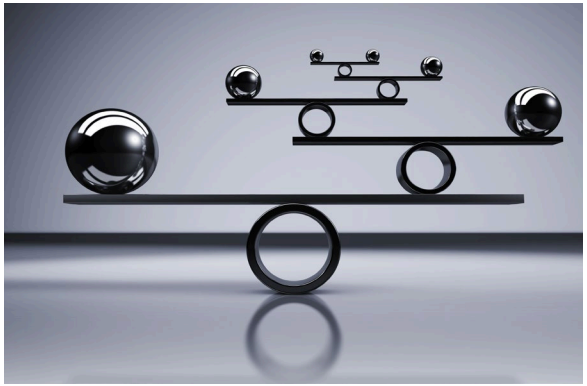
Applies to: MCW Faculty/Staff/Students involved in human research who perform research activities which result in billable professional services.

PURPOSE: The purpose of this Standard Operating Procedure (SOP) is to provide guidance to ensure consistency with compliant research billing practices. By doing so, minimizing financial risk to clinical trial participants along with financial and non-compliance or litigation risk to the institution.

In accordance with Centers for Medicare & Medicaid Services Clinical Trial Policy (NCD 310.1) qualified billing of research related procedures, items and services may occur.

SCOPE: This applies to all faculty and staff involved in research at the Medical College of Wisconsin (MCW), Froedtert Hospital (FH), Children's Wisconsin (CW) and Versiti/Blood Center of Wisconsin, who will perform research activities which result in billable professional services

How Much Time Does Qualtrics Take?



CRC Responsibilities

- Subject (Do No Harm)
- Institution (MCW, Facility, PI)
- Sponsor (Protocol Owner)

How the Completed PB Survey Submission Fits?

- Fulfills CRC Responsibility
- Takes 10 minutes of CRC time
- Completed by 24 hours of visit/procedure provides all the Details for Compliant Claims Management

Are the Professional and Hospital Claims for all Studies You Support Compliant?

Ready for that Corporate Compliance or Medicare Audit?

Need Help?

Sue Mauermann
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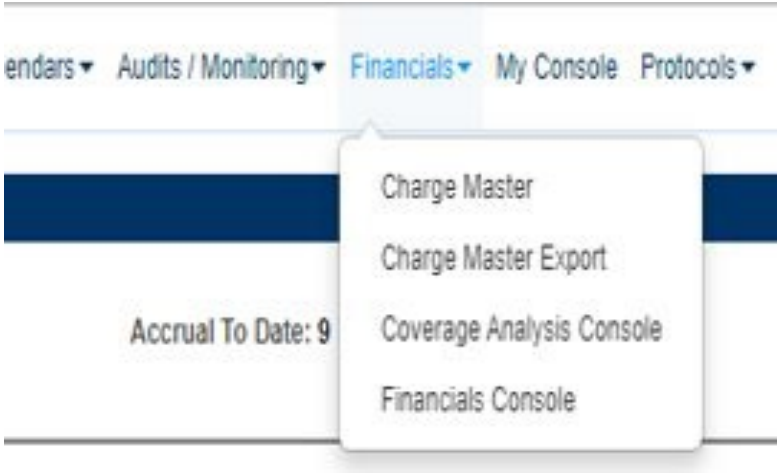
Qualtrics - Bridge to Next Steps for Financials

- The Financials Project includes development of standardized processes for all steps of the process from Coverage Analysis & Budget Development to Final Account Reconciliation
- Will be a two-phase Process, lasting 18-24 months
- Launch anticipated early Summer 2022
- Support is across F&MCW Leadership (Research, Finance, Compliance, EPIC)
- Documentation of Current Workflows in progress
- Will include the OnCore Financials functions to support the New Financials Standardized Process



*Does Your Department Utilize OnCore Consistently?

*Do The Protocols You Support Have OnCore Calendars?

If Yes, Are All Subject Visits Up To Date In The OnCore Calendars Within 24 Hours?

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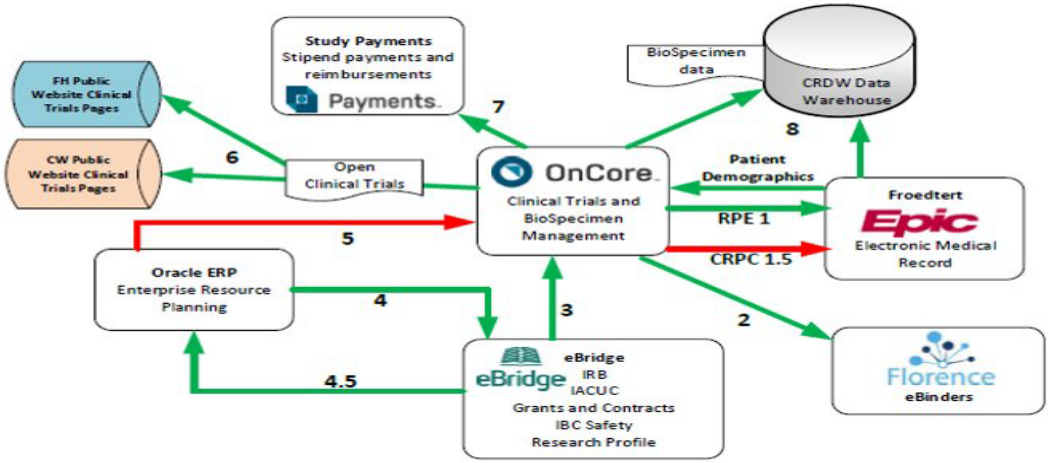
Ability to Use the OnCore Financial Console Functions in the future is 100 % Driven by Consistent Use of the OnCore Calendar *

Forms	Treatment REG : REG Registry Arm Screening 1@1Days	1,2,3,5 years post enrollment (REG arm only) 2,4,6@6Years			
	Screening	Y1 REG arm	Y2 REG arm	Y3 REG arm	Y5 REG arm
Informed Consent	NA [17]				
Treadmill Stress Test	X [17]				
TS Risk Score	NA [17]				
dical History	NA [17]				
al Assessment	S [17]				
	NA [17]				
	NA [17]				

Research Systems Integrations



1. **Epic RPE:** New study information; study and patient status changes

1.5 **Epic CRPC:** Study Visit standard of care versus Research billing data (PENDING)

2. **OnCore-eBinders interface:** creates template eBinder structure for OnCore Protocol with study staff pushed and mapped to roles on the eBinder created for the study.

3. **eBridge Interface:** IRB Protocol #, statuses (PRO, AME, RE, CPR), approval dates, expiration dates, review information, committee, etc.

4. Daily feed of employee/worker information, Department/Division information

4.5 Funding Proposal and Budget information; eBridge data pushed daily for account setup in Sponsored Programs

5. OnCore & eBridge accounts to be matched to records in Oracle for accurate user and dept/div information (PENDING)

6. **Study Information Portal (SIP):** sends open clinical trial information from OnCore to FH/CW public websites

7. **OnCore – Payments interface:** Subject information on OnCore Protocol sent to Study Payments

8. **OnCore-Epic Integration to CRDW:** BioSpecimen data sent from OnCore and de-identified Epic data copied to CRDW for data mining.