Research Billing Compliance
University of Iowa Health Care

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Patient Financial Services
Research Billing

• **Who we are:**
  ◦ Group of seven staff within Patient Financial Services

• **What we do:**
  ◦ Help researchers bill for clinical trial services appropriately and in compliance with applicable laws, regulations, and policies

• **How we do it:**
  ◦ Develop a Research Billing Plan before a study begins
  ◦ Review and direct the research subjects’ UIHC charges in Epic appropriately (to the study or to insurance) based on the approved Research Billing Plan
The University of Iowa Human Research Protection Program (HRPP)

UI Institutional Review Boards
- Biomedical (IRB-01) & VAMC (IRB-03)
- Behavioral/Social Science (IRB-02)

IRB Reliance Model: SMARTIRB

Commercial IRBs
- WIRB, Quorum, Schuchman, Chesapeake

IRB Consortiums
- National Cancer Center Institute IRB (NCICIRB)
- Greater Plains Collaborative (GPC), StrokeNet, CREATE

Research Integrity Officer

Office of the Vice President for Research
Vice President for Research & Economic Development

Assistant VP for Research Administration/
Institutional Official

Division of Sponsored Programs

Human Subjects & Conflict of Interest Office

Environmental Health & Safety Office

Institutional Biosafety Committee

Stem Cell Committee

Medical Radiation Protection Committee

Additional Entities
---Related policies governed by the UI Operations Manual and UI Health Care
---UI HIPAA Privacy Officer and Security Officer
---UI Accounting Services & Grant Accounting
---UI Information Technology Services
---ICTS Clinical Research Unit

The University of Iowa

Holden Comprehensive Cancer Center
Protocol Review & Monitoring Committee

UI Hospitals & Clinics:
- Pharmacy & Therapeutics (P&T) Committee
- P&T IDS (Inv Drug Service)
- JGC Research Billing & JGC CCMS
- Nursing Research Committee (NRC)

Research Counsel

Conflict of Interest in Research Committee

Last revised 1/2018

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“Other Committee” relationships with research projects that may affect the University of Iowa IRB review, approval, or release

Review/Approval required before IRB Review:

PRMC: Holden Comprehensive Cancer Center Protocol Review and Monitoring Committee
CIRC: Conflict of Interest in Research Committee
IBC: Institutional Biosafety Committee
JOC: Joint Office for Compliance

Approval required before IRB approval:

P&T: UIHC Pharmacy & Therapeutics and Pharmacy & Therapeutics Investigational Drug Service (IDS)
MRPC: Medical Radiation Protection Committee
NRC: Nursing Research Committee
VA P&T: VAMC Pharmacy & Therapeutics
VAMC PO & ISO: VA Privacy & Security Officers

Approval required before HSO release of IRB approval:

DSP/CTO: Sponsored/Industry Funded Protocols Only
JOC/CMS: Medicare approval for device trials only**
VA R&D: VAMC Research & Development

* In general if the IRB of Record is an IRB outside of the University of Iowa designated IRBs (IRB-01, IRB-02, or IRB-03), all committee approvals must be in place prior to the external IRB submission & review.

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Importance of a Research Billing Compliance Program

- Large academic medical centers are decentralized and vulnerable to billing compliance risks

- Medicare’s Clinical Trial Policy may limit coverage of some clinical trial services, but allows for other services to be billed

- Services that are paid for by study sponsors cannot be billed to third party payors

- Helps protect our research subjects and their insurance payors from getting billed for services that shouldn’t be billed

- Helps protect our principal investigators from the risks of False Claim Act violations
Settlements related to improper research billing

Cases of improper clinical trials billing\textsuperscript{6-12}

- Johns Hopkins: $2.6
- Cornell University: $4.3
- Rush University: $1.1
- Northwestern: $5.5
- Beth Israel: $2.4
- Yale University: $7.6
- Mayo Clinic: $6.5

\textsuperscript{6-12} in millions

Applied Clinical Trials, Jan 22, 2013
Medicare Clinical Trial Policy

- Study must be a qualifying clinical trial
- Item/service must be a routine cost
- If sponsor provides funding, may not bill Medicare, even if routine care
- All other Medicare general rules must be met
- Must be consistent in language related to who will pay: contract/grant, protocol, consent document, billing plan, budgets
- If promised free in consent document, can’t bill to Medicare. Sponsor agreements and consent documents have billing implications
- Every study should have a Coverage Analysis before it begins
Coverage Analysis

• The process of reviewing the study documents (protocol, consent document, sponsor agreement, budget) to determine which study-related items and services are billable to Medicare and other third party payors, and which are not

  o Research Billing may suggest or require changes to the Costs section of the consent document

  o All study documents (consent, budget, contract, billing plan) must be consistent in terms of the payor of study services
Coverage Analysis (cont.)

- The Coverage Analysis is an objective process

  - What tests and procedures are required by the protocol and at what time points? (protocol’s study calendar, footnotes)

  - What is promised for free in the consent and/or documented as being provided by the sponsor in the clinical trial agreement and/or budget?

  - What, if anything, is limited by Medicare’s regular rules and regulations?

  - For any tests and procedures left after these items are carved out – the PI must determine what is routine care and medically necessary for patients with the disease or condition
RB Process/Requirements for Researchers

Prior to IRB approval:

1. RB will receive an automatic notification when you submit your application in HawkIRB if question V.25 ("Will the study involve . . procedures, tests, evaluations . . .?") is answered Yes

2. RB will complete a Coverage Analysis and develop a Research Billing Plan for the study
   - Please respond to questions from RB staff as they complete this process
   - Investigational device and carotid stent trials may have more requirements (submission to and approval from Medicare of the trial)

3. Obtain the PI’s signature on the Research Billing Plan, and return a signed copy to RB
   - RB will then upload an approval memo in HawkIRB
   - The HSO will place a hold on release of external IRB studies and will not schedule an internal IRB study application for a full-board meeting until the approval memo is received
RB Process/Requirements for Researchers

After IRB approval/study begins:

1. Associate the subject to the study in Epic the same day the consent is signed
   - Enter Status as “Enrolled” or “Consented – In Screening” (OnCore users have additional Active statuses to choose from)
   - Add the Active start date (date consent signed)
   - As of 2/12/18, associating the subject to the study in Epic replaces the paper Record of Consent

2. Link the appointment or encounter to the study if possible

3. Respond to inquiries from RB staff re: charges generated in the Epic billing system for enrolled subjects (i.e., whether the charges are study-related or not; whether they should be billed to the study or insurance). RB staff uses the Research Billing Plan as a guide but may have questions about charges
RB Process/Requirements for Researchers

After IRB approval/study begins:

4. Change the Status and enter an End date in Epic when the subject’s participation in the study has ended

5. Notify RB if the protocol is modified and the modification affects the Research Billing Plan (some protocol modifications for investigational device/carotid stent trials must be submitted to Medicare)

6. Notify RB when a the study has ended or is closed
RB Process/Requirements for Researchers

Key Step: associate the subject to the study in Epic the same day the subject signs the consent *OnCore users have a different process for associating subjects to studies

- Allows the system to work properly and avoids the need for RB and Patient Financial Services Special Programs staff to make charge corrections
- Appends Medicare and other third party payor-required coding to the claims
- If associating the subject to the study the same day is not possible or is missed – contact RB with IRB #, subject name, MRN, date consent signed

*Since associating the subject in Epic replaces the paper Record of Consent, RB staff can no longer associate subjects to studies on behalf of the research team
RB Process/Requirements for Researchers

Key Step: associating the subject to the study

• Only the two Active statuses in Epic will hold charges for review by RB:
  o Consent – In Screening
  o Enrolled
  o OnCore users have additional Active statuses to choose from

• If a subject is associated immediately with an Inactive status, charges are not stopped for RB review! Association must be made with an Active status before changing to an Inactive status. Examples:
  o You get a lab result back the next day which makes the subject ineligible and you forgot to associate the subject the day before when s/he signed consent – don’t associate the subject with an Ineligible status or the lab charges will not be held
  o You associate the subject as Identified then change to an Inactive status (Withdrawn, Ineligible) without changing to an Active status in between

• Remember to enter an Active start date

• Link the appointment or encounter to the study if possible
Subjects’ charges are held in Epic – RB moves the charges into the correct bucket

- Standard of Care
  - Not Related to Study

- Study Only
  - Paid by Sponsor

- Both Standard of Care and Study Related
Research Billing Terms & Definitions

- **Study related**: A service/procedure that must happen for a research study and occurs after the subject has signed the research consent. Study-related services may bill to insurance (designated as SOC on the Research Billing Plan) or to the study (designated as RS on the Research Billing Plan)
Research Billing Terms & Definitions

- **Standard of care (SOC):** A study-related service that *also* happens as part of a subject’s standard medical care *and* is not promised free from the sponsor is designated as SOC on the billing plan. **SOC services bill to insurance.**

- **Research sponsored (RS):** A study-related service that *only* happens for research, *or* is promised free from the sponsor (even if it is part of a subject’s standard medical care) will be designated as RS on the billing plan. **RS services must bill to the sponsor.**
Coordinators: how you can help!

• **Clarity of study documents**
  - Consent, protocol, and HawkIRB application consistent in the description of procedures
  - Internal/external budgets – if you indicate in HawkIRB that there is an internal or external budget (questions V.25.e, V.25.f), either attach them in HawkIRB or email them to us
  - Review the Research Billing Plan that RB creates – is it accurate?
  - Costs:
    - Is the consent, budget, and sponsor contract consistent in who is paying for what?
    - Suggested language on RB page on The Point

• **Consent process**
  - Help the subject/family members understand what is/is not provided for free and that they are responsible for co-pays and deductibles
  - Pre-authorization with the subject’s insurance company
  - Medicare Advantage (Medicare managed care plan) – costs may be incurred when participating in a clinical trial; advise subject to talk with someone at their plan
Coordinators: how you can help!

• Help your PI
  o If the PI obtains informed consent - do not promise services for free if they’re not!
  o Documenting “screening for study ABC” in the medical record is a problem if the office visit was standard care – this negates the therapeutic intent of the trial

• Communicate
  o Timely association of the subject to the study in Epic and timely update of status changes; notification to RB of the study ending
  o Reply promptly to questions from RB about charges – large $ accounts are held until we review and release them
  o Notify RB of an Adverse event – charges to be billed to study
Important Final Reminders

Prior to IRB approval:

1. In the HawkIRB New Project Application, list/describe all of the places study procedures will take place

2. Review the Research Billing Plan and make sure it is correct before the PI signs it

After IRB approval:

3. Associate subjects in Epic in a timely manner – must associate same day as consent, ideally before any services are performed

4. Keep Status and End Dates updated in Epic

5. Answer emails from Research Billing staff in a timely manner
Contact Us

• The Point: https://thepoint.healthcare.uiowa.edu
  ◦ Policy information, Medicare guidance, pricing tools

• Email: researchbilling@healthcare.uiowa.edu
Questions