

Clinical Research Billing (CRB) Compliance – Financial Impact

May 20, 2021

Virtual Conference H20

Sarah G Hull, FHFMA



WHY WE'RE DIFFERENT

Collaboration allows us to achieve a level of success we never thought possible.

When talented individuals from different backgrounds are brought together and encouraged to work as a team, the result is innovation and success. Our unique blend of subject-matter expertise, wealth of cross-disciplinary and **cross-industry experience**, and proven track record enable us to deliver tailored, effective solutions and unparalleled service in a broad range of matters.

Our clients feel the positive energy our teams bring to the table and appreciate that they are gaining a partner with not just one area of expertise but with many. This **willingness and eagerness** to work together to provide the best solution for our clients is at the heart of why Ankura is able to achieve success with our clients.



Solutions

- Healthcare Compliance
- Healthcare Analytics
- Research Consulting
- Physician Consulting
- Hospital and Health System Consulting
- Revenue Cycle Management
- Transaction Advisory and Valuation Services
- Payer Advisory Services
- Strategy & Performance

Clinical Research is a Critical Component of Our Health Care System

Clinical research is a branch of healthcare science that **determines the safety and effectiveness** of medications, devices, diagnostic products and treatment regimens intended for human use.

Clinical Research is Complex



Intellect



Funding



Commitment



Patience

As institutions and practitioners pursue clinical research opportunities, they should have **established administrative and operations processes** to support their clinical research management and billing.

Benefits of Established Processes



Mitigate Billing Compliance Risks



Support Efficient Clinical Research



Contribute to the Overall Research Strategy



Ensure Financial Success

Clinical Research Billing Workstreams

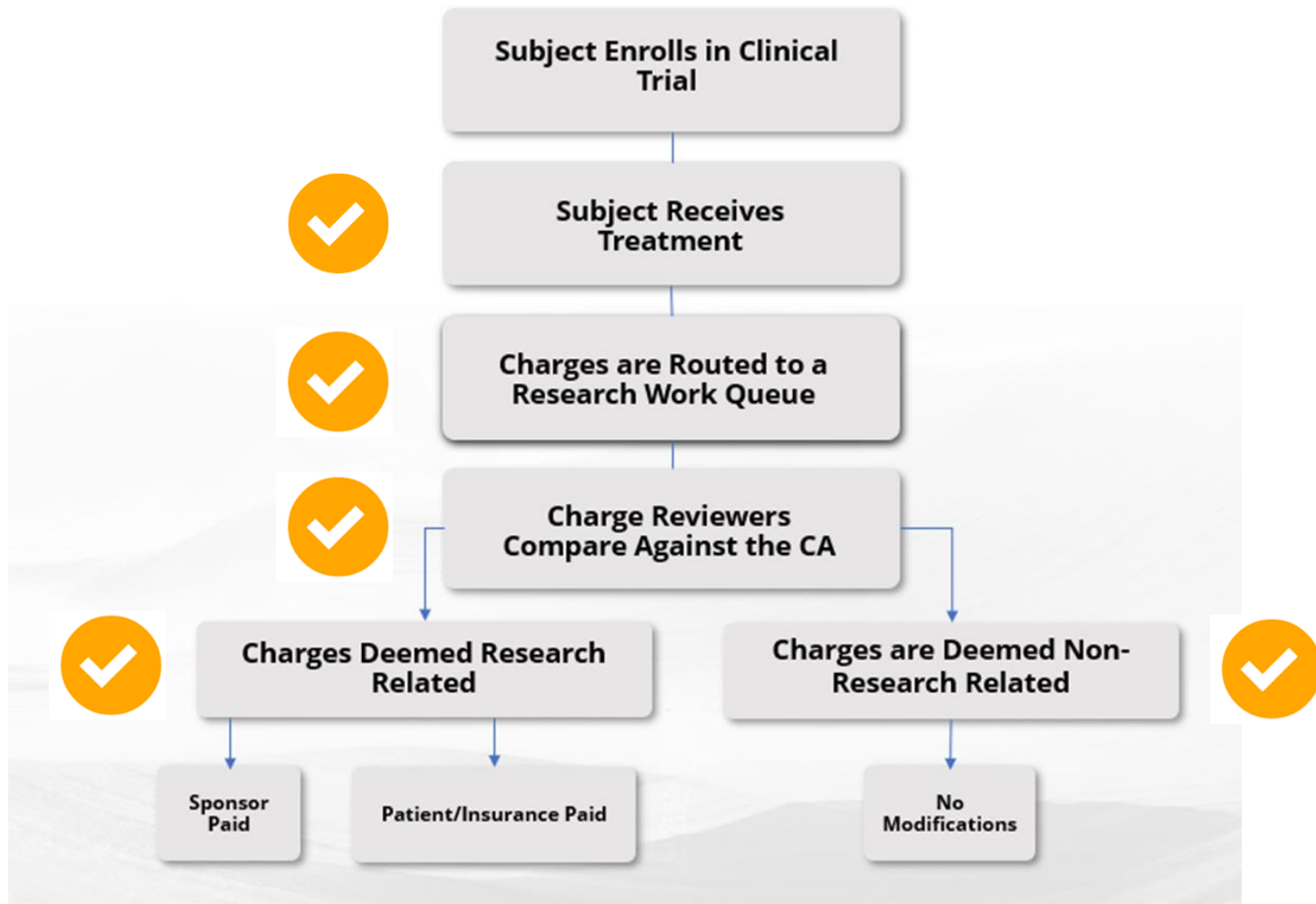
1. Feasibility Assessment
2. Study Intake
3. Grid Development
4. Coverage Analysis
5. Coding

6. Upload
7. Delivery
8. Internal Budget Development
9. Budget Negotiations
10. CTA Negotiations

11. Document Harmonization
12. Research Claims Scrubbing
13. Sponsor Invoicing
14. AR Management



Possible Breakdown Areas



Possible Breakdown Areas

Revenue Cycle Area	Research Actions
Registration	<ul style="list-style-type: none"> • Research billing account • Billing system flags for study • Study budget in place
Scheduling Charges are deemed Research or non-Research	<ul style="list-style-type: none"> • Identifying study participants – link study to encounter • Start and end dates of participation • Enrolled and disenrolled status for patients • Billing direction – all to study, all to patient/insurance, both study and patient/insurance
Financial Clearance	<ul style="list-style-type: none"> • Understand patient's insurance coverage requirements for non study service • Confirm coverage • Sponsors may or may not pay when insurance denies
Charge capture/charge entry Subject Receives Treatment	<ul style="list-style-type: none"> • Research billing grids • Develop internal indicators to route charges in mixed visits • Medical record documentation

Possible Breakdown Areas

Revenue Cycle Area	Research Actions
Charge Routing Charges are Routed to a Research Work Queue	<ul style="list-style-type: none"> • Understand and test system capabilities to map appropriate services to sponsor or patient's insurance
Billing Charge Reviewers Compare Against Coverage Analysis (CA)	<ul style="list-style-type: none"> • Invoicing studies applying negotiated rates • Billing participants/insurance (where applicable) • Ensure correct Medicare coding - modifiers for routine costs, investigational, etc... • Collecting from sponsors
Auditing	<ul style="list-style-type: none"> • Facilitates correction of identified billing errors • Points to areas needing process improvements • Identifies topics on which faculty and staff need additional training

Sponsor Invoicing Risks

Appropriate Billing is dependent upon access to the negotiated internal budget and amendments

- Clean identification of subject care costs (Cost Per Patient), administrative costs (set up, close out, other administrative fees), and any indirect overhead costs.
- Billing for services that are paid for by the sponsor
- Billing for services that are promised free in the informed consent
- Billing for services that are for research purposes only
- Billing for services during a non-qualified clinical trial
- Billing Medicare Advantage plans for services that should be billed to the Medicare Administrative Contractor

Sponsor Invoicing: Grid Development

Appropriate billing is guided by a sponsor invoicing grid which delineates the services provided within the study, routine costs and reflects the negotiated budget, informed consent, protocols and applicable amendments.

- Invoicing Grid is often the basis for charge entry
- Identifies services covered by the study and associated
- Identifies Routine Costs – items or services covered by Medicare during a qualifying clinical trial
- Appropriate modifier identification
- Establish Pre-bill Work Queues

AR Management

AR management: full understanding of how each area or department relates to, and influences services billed to sponsors or patients

- Collecting AR: Understanding the study budget and services billable to the sponsor, the patient, or both.
- Effective Sponsor Invoicing including effective Grid Development and management

Sponsor Invoicing Risk Impact AR

Appropriate Billing is dependent upon access to the negotiated internal budget and amendments. Improper billing reflects negatively on AR and increases the need for management.

- When a research entity takes money for a clinical service from a sponsor, that service cannot be billed to the subject/patient's insurance.
- Billing for services that are promised free in the informed consent.
- Billing for services that are for research purposes only.
- Billing Medicare for services during a non-qualified clinical trial.
- Billing Medicare Advantage plans for services that should be billed to the Medicare Administrative Contractor.