Beyond Industry Trials: Clinical Research Billing and Finance in Awards and "Unfunded" Studies

Clinical Trial Office
Center for Clinical Research Advancement
Clinical Research Resources Office, Clinical Research Seminar, February 2025

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Primary Learning Objectives

By the end of the seminar, participants should be able to:

- Explain the operative definition of "**clinical research**" in CRBF
- Identify the full range of clinical research studies that are subject to CRBF requirements
- Discuss key features of CRBF compliance
- Locate resources for learning more about (or refreshing one's memory of) BMC/BU CRBF process and federal requirements

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Use of technical terms and distinctions

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Clinical trial, clinical research

Clinical trial (CT)

- Means different things to different people or in different contexts
- Can be any CR study, interventional study, treatment study, a drug trial
  - CT as CR = use of "trial" as "attempt," "assay," "experiment," "examination"
  - **Intervention** = test object is diagnostic or treatment (has therapeutic intention)
  - **Treatment** = drug, device, practice/therapy (acupuncture, yoga, music)
  - **Drug trial?** Medicare's rule allowing billing related to CTs excludes device trials
- Some also equate CTs with **industry-sponsored** CTs

Clinical research (CR), in the context of CRBF

- Any study including **≥1 prospective** clinical procedures, services, or other items
  - Item ranges from buccal swab/blood draw to organ transplant

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CRBF, RB, RBC, RBC assurance

Clinical Research Billing and Finance (CRBF)

- Entire process of clinical research finance of a given study, from **feasibility to closeout**
- Equivalent and nationally referred to as "**research billing**" and **"RB"**
- Used to avoid impression that RB covers only EMR billing of patient care services

Research Billing Compliance (RBC)

- What is/needs to be done to meet **federal** and **institutional requirements**
- Sometimes interchangeably used with the process (RB or CRBF)

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In CRBF, "billables" = "patient care billables"*

Billables are clinical items or services that:

1. **Are** billed via medical coding **through Epic**
2. **Could be** billed through Epic, *or*
3. **Should be** billed (through Epic or some other pathway) but **were not**

Type 1 is narrow and excludes, e.g.:

a. Clinicals done and billed **by effort**
b. Items purchased by or provided to the study for **related services** by effort
c. Core/**service center** offerings (eg, GCRU, CRU, radiology core)

Difference between billables type 2 or 3:

- Type 2: alternative invoice/reimbursement pathway (a-c)
- Type 3: **failure of billing**, intended or not

****Even if the participant is not an actual patient, e.g., healthy participant in a Phase I trial***

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Standard (industry) CRBF process

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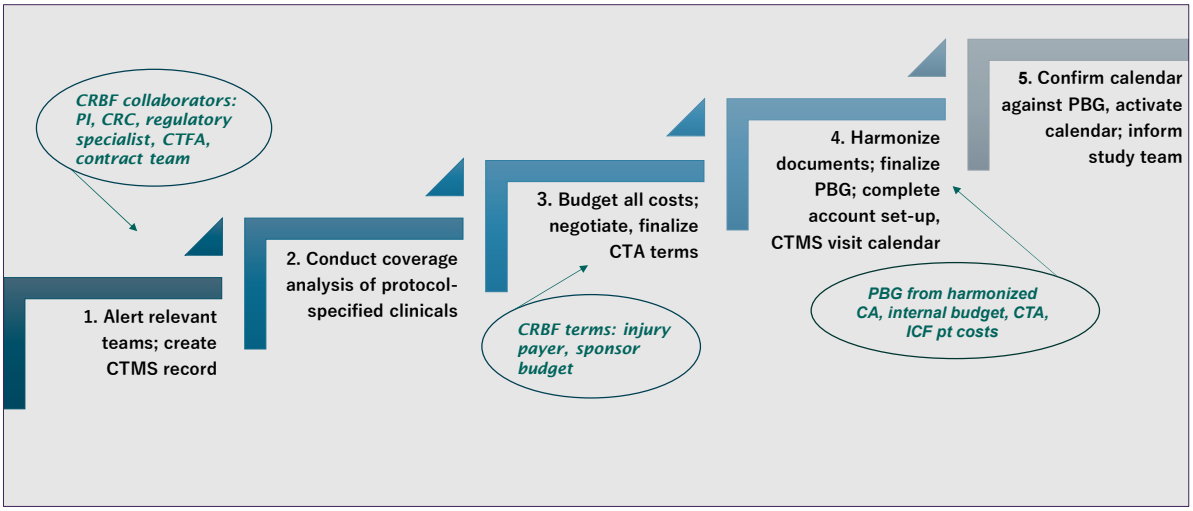
Front-end CRBF workflow



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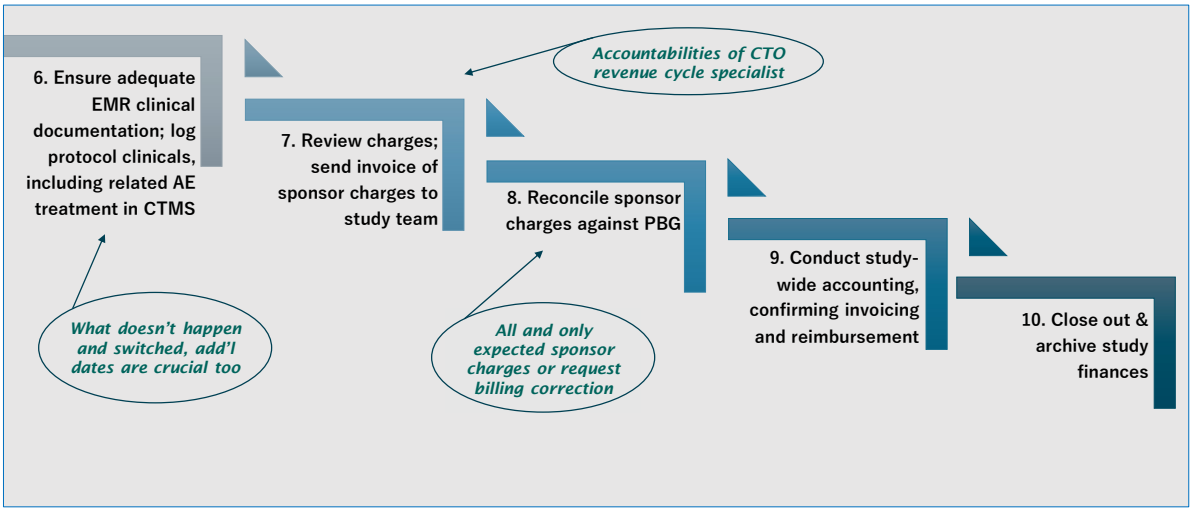
Back-end CRBF workflow: from first visit to close-out



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CRBF differences by sponsor type

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CRBF differs somewhat based on sponsor type: industry

The sponsor type most associated with clinical trials

- Typically, most common sponsor
- CRBF standards for **start up** are paradigmatic
  - Almost always, **no protocol development**
  - Protocol-specified services are identified; **coverage analysis precedes internal budget**
  - Terms are negotiated: cost of budgeting should be covered if not specified
- **Payments** are often **automatic**, by **milestone achieved**
- **Sponsor queries** (= late costs) may drag out much longer than end of study visits
- At BMC, **CTO** provides central oversight
- At BUMC, the **Sponsored Programs** office and **CTO** share central oversight

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CRBF differences by sponsor: federal*

Federal awards are paradigmatic

- **State, city** tend to follow federal rules*
- **Financial non-compliance** risks are higher than non-government-funded projects
- **Proposal development and submission include budget**: prohibited from being funded
- Financial reporting and closeout are more complex
- **Budget periods** are typically annual – award amounts can change over time
- **Foundations** share some of the above, eg, proposal development, but **rules vary widely**
- At BMC, research administrative oversight is spread over multiple teams
  - CTO, Sponsored Programs Administration (SPA), Sponsored Programs Finance (SPF)
  - Also, in some cases, Strategic Research Growth (SRG), which assists PI in proposal development

**State and city funding tends to derive from federal agencies, who hold them accountable; in some cases, separate MA laws reflect federal terms*

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CRBF differences by sponsor: "unfunded" studies

"Unfunded" is a misnomer: such studies are internally funded

- ***No research is without cost***
- Typically, residual balances from industry studies are used
  - Therefore, the funding is BMC or BUMC's
  - Transfer of funds to a department or individual is at the **discretion of the institution**
- Some ethics and compliance risks are higher due to:
  - **Absence of** external sponsor ***oversight***
  - Greater ease of bypassing central administrative offices = potential for a second reduction of oversight
  - Resulting potential for ***misunderstanding requirements***

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CRBF process	Award	Internally sponsored	Industry contract
Central offices involved	CTO and SPA/SPF or OSP	CTO and SPA/SPF or OSP	CTO/BUMC OSP
Feasibility review	Chair/chief/sponsor review	+ Prior chair/chief okay	+ Prior NDA/CTA
Coverage analysis (CA)	**Informal prior to proposal submission; formal at Just-in-Time or time of award**	**Prior to costing of patient care charges, effort**	
Internal budgeting	Before proposal submission but **awaiting CA for routine costs**	**Often thought unneeded; department accountability to ensure resource protection**	May start early; must account for CA; may need alteration after negotiations
Site-sponsor agreement	Award acceptance	**Chair/chief approval**	CTA negotiation to final budget/injury terms
Account set-up	Post-agreement; may vary in timing after agreement		
Document harmonization, final billing plan, Velos calendar set-up	Analogous to IRB approval, prior to first participant's first visit		
Study visit documentation	Comprehensive clinical services including those missed, those related to AEs		
Billing review	Requires complete visit data related to patient care; results in claims, internal invoice		
Charge reconciliation	Monthly QA: all charges to sponsor accounted for; no patient charges mistakenly charged		
Sponsor invoicing, payment verification	**Study team confirmation of central office/vice versa**	**Confirm internal payments to any/all service providers**	Identify non-auto invoicing; confirm all payments
Account reconciliation and closeout	Varies by sponsor; feds' rules, numerous; include **final reports**	**Follow Generally Accepted Accounting Principles (GAAP)**	Varies by sponsor; follow GAAP

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Ethics and compliance requirements

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CRBF ethics and compliance, *aka* RBC*

Ethics is infrequently invoked in RBC, but

- Misbilling patients is failure of **participant protection** ethically
  - Applying the Belmont principles of respect, beneficence, and justice
- Charging government inaccurately is **theft of taxpayer dollars**
- Both are ***fraud***

CRBF is subject to *loads* of compliance requirements

- Includes sponsor rules, (additional) government requirements, and institutional policy
- Government wields the biggest stick(s), including:
  - Exclusion from CMS participation
  - Exclusion from HHS or other US sponsorship, and, more likely
  - Adjudication of identified ***False Claims Act*** violations

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Top two federal departments with CRBF oversight

Department of Health and Human Services (HHS)

- **Centers for Medicare and Medicaid Services** (CMS): via statute (law), regulation (Code of Federal Regulation), national and local coverage determination (NCD/LCD)
- National Institutes of Health (NIH) **policy requirements** include CR stipulations
  - NIH Grants Policy Statement (NIHGPS) requires routine hospital services to be billed to insurance

But Department of Justice (DOJ) is their enforcer

- Typically, operates against healthcare research entities via **settlement**
- **Criminal charges** are possible, but infrequently applied to researchers, research sites

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Since Lincoln signed the FCA into law in 1863

The DOJ has recovered many billions*

- Civil and potential criminal penalties
- Applicable to individuals, but institutions take the biggest hit
  - *Thus* **patients, employees, institutional reputation** are thereby hit
- False = knowing submission of false claim, but includes **unintentional negligence**
- Wide compass, including, but not limited to:
  - Medical **billing** of gov't-insured patients (= high percentage of our participants)
  - Time and **Effort reporting**
  - Little known **NIH rule** requiring routine hospital charges to be billed to insurance
  - Procurement of goods, services, consultants**
- Note: billing and effort reporting risks apply to **all sponsor types**, even ***internal***

****In FY2024, DOJ recovery was >$2.9+B, >$1.67B from healthcare industry***

*****We exclude discussion of procurement, subject to FCA and specific procurement laws; for those interested, there's a training tomorrow, 2-3:30 pm; see the research education webpage for the Zoom link or, soon, the recording***

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FCA violations reporting and costs

Commonly, FCA violations are via self-disclosure or whistleblower complaints

- Potential **whistleblowers** are incentivized by up to ***30%*** of a given settlement
- In 2024, Moffitt Cancer Center and Research Institute: ***$19.565m***
  - "For improper claims submitted to [CMS for ineligible] patient care items and services provided during research studies…."*
- **Additional costs**: legal, extra staffing, low employee morale/loss of staff, loss of trust
- By **self-reporting** and otherwise cooperating, Moffitt avoided CMS exclusion and greatly reduced its fine**
  - Law allows for high-dollar penalties ($14,309-$28,619 per claim in 2025) plus 300% of damages

**DOJ report, January 2024*

***https://www.jdsupra.com/legalnews/moffitt-center-s-fca-settlement-is-3185984/*

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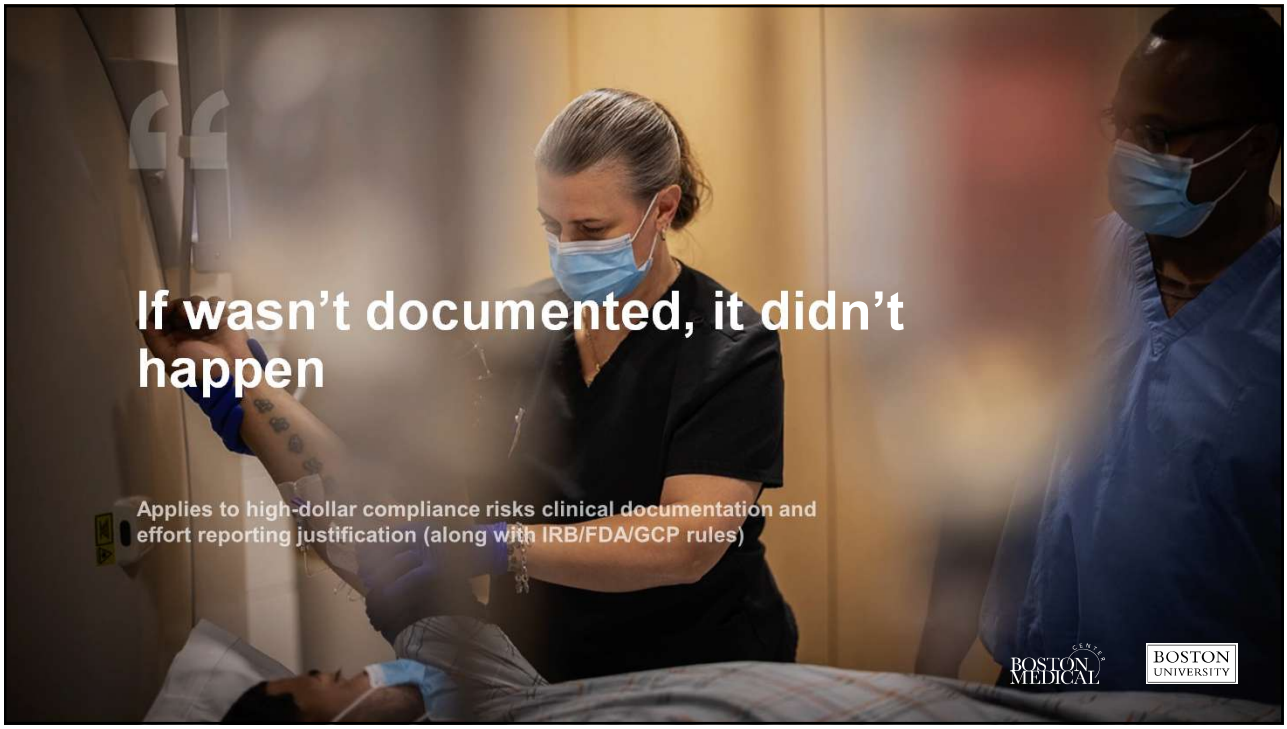

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CMS demands compliance beyond 1:1, clinical item and charge

Adequate clinical documentation (= in EMR) supporting CMS charges

The best price among all payers (except Medicaid)

- If BMC charges a sponsor $0-<CMS rate, BMC sets new CMS rate
- CR **financial reconciliation** therefore includes confirming:
  - Every clinical item is charged at **≥CMS rate to sponsor or participant/insurance**
  - All sponsor charges are **internally invoiced** to study, **externally reimbursed** by sponsor
- Vague CTA terms are **not exculpatory**
  - If a clinical service is by effort, rather than CPT code, it is charged to the study as such

Applies to all studies, externally and internally sponsored

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Effort across study types

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Effort reporting risk applies across sponsor types

If person performing effort has any government funding

- But, first, studies receiving **federal, state, city funding** face direct risk
  - **Over-reporting** effort is an **FCA violation**
  - *Re* state funding, not just about pass-through federal funding: MA has its own FCA
  - *Re* city funding, to confirm no direct risk, must confirm that $$ do not come from US, MA
- Then, **foundation awards**– *risk mostly indirect*
  - But fraud and contractual violations are not limited to relations with government

All studies face indirect risk = if personnel effort is gov't paid

- If effort report requires gov't funders, it is subject to **single audit**
- Annual "single audit" applies to all research sites with $750k-1m* in federal funds

If even an unfunded study includes personnel on gov't funding, effort reporting matters

****Threshold increased by 33.33% this year; the new threshold applies to BMC now and BU in its upcoming new fiscal year***

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Effort and its risks are central to all CR sponsor types

No matter the sponsor type, effort can be a significant FCA risk

- Most obvious: effort reporting of items that were **billed via Epic** or core/service center
- Less obvious, likely more common: reporting without process, document follow through
- Clinical services by effort are legitimate, when **documented sufficiently**
  - Consistent CRBF **effort-related documents** (all)
  - Effort that is **justifiable** upon audit
  - Consistent **salary allocation** to sponsor
  - Effort report percentages that are consistent with all above
  - Documentation of reasons for any apparent divergence

Do not forget risk of non-effort items, if they are susceptible to charge doubling

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NIH restrictions on patient care costs

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The gist: NIH policy prohibits* paying for "usual care"

Makes sense: have insurers pay for medical necessity

- = saving taxpayer $$, when insurer isn't CMS
- = saving research $$, when insurer is
- Refrains from mention of **participant injury** – but that's usual care
- Is virtually silent on professional billing (PB)
  - Possibly because of complexities of untangling effort and patient care charges

Note, however, NIH makes rooms for special exceptions

" Usual care is care that would have been incurred even if the research study did not exist. The patient and/or third-party insurance generally will provide for reimbursement of charges for usual…care"

NIH Grants Policy Statement, 19.2 Definitions

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The details: three exceptions apply

Two require the enrollment to be "of research importance"

- If the potential pt's **data are crucial**, the NIH will pay when they
  1. Are **un- or under-insured**, the latter of which requires a special billing adjustment* or
  2. Make participation contingent upon the NIH paying, refusing to pay or have insurer billed
     - Here, the PI has a "special responsibility" since usual care is pt/insurer responsibility

One addresses a medically unnecessary, research-only inpatient stay

- = **no health care advantage** may be expected from the hospitalization
- Yet **pt requires outpatient care**, either known or unexpected
- Reveals NIH awareness of complexity of separating inpatient-outpatient services

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General takeaways: awards and Internally sponsored studies

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CRBF rules and governing bodies apply

We tend to equate clinical trials with industry trials

- Which face **significant** ethics and compliance requirements and financial accountabilities
- Awards and "unfunded" studies escape neither
  - Are, in fact, **higher risk** in different ways

Whenever something clinical is happening in any study, we should:

- Remind ourselves of value of **responsible resource allocation** to our patients, colleagues
- **Salute our longstanding dedication** to the research community, and
- Alert the **CTO**, the BMC-BUMC shared service charged with assisting CR studies

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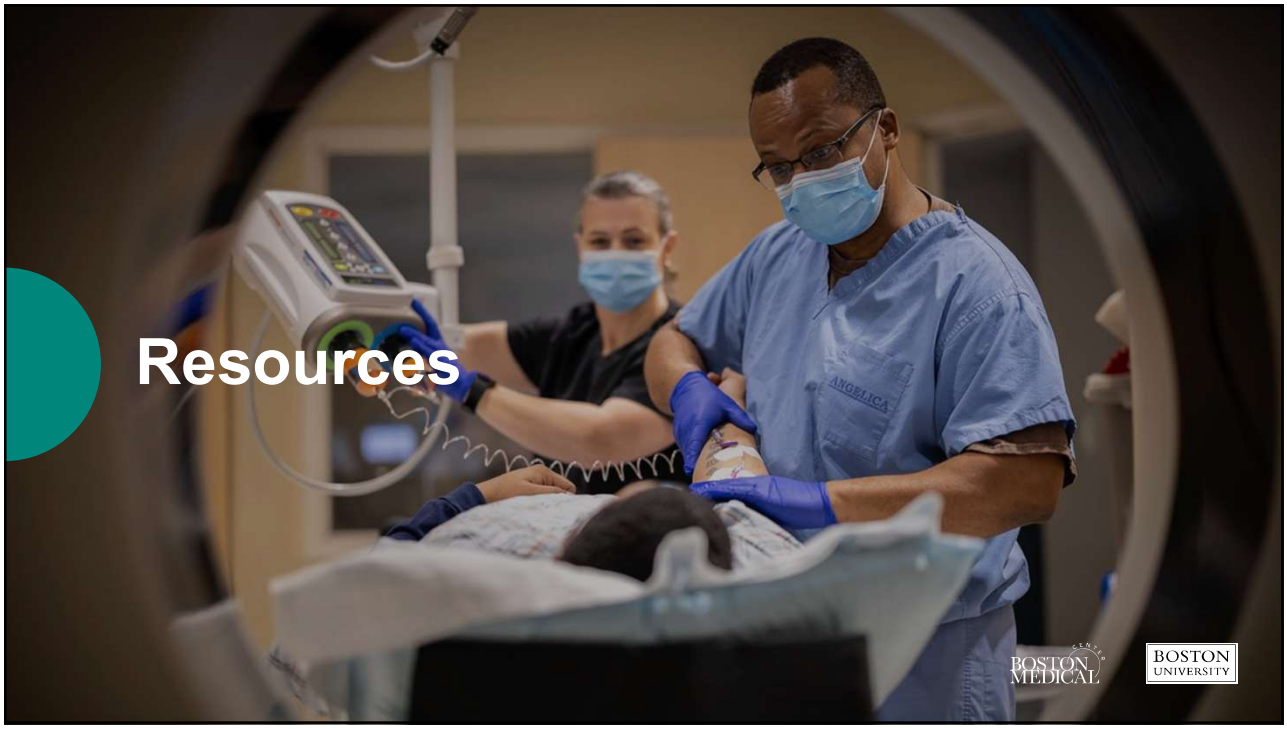

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BMC/BU

- ***Coverage Analysis policy***, access via use of BMC log-in
- ***CRBF training library***, topics include RBC basics, CRBF process, internal Budgeting, effort in CR, budget negotiation; coming soon: document harmonization
- ***Center for Clinical Research Advancement***, home page, including link to ***CTO pages***
- ***Sponsored Programs Finance***, home page with many related links
- ***Sponsored Programs Administration*** home webpage, including introductory guides to awards administration
- ***Effort Reporting, BU Office of Research***
- ***BMC Closeout Process***

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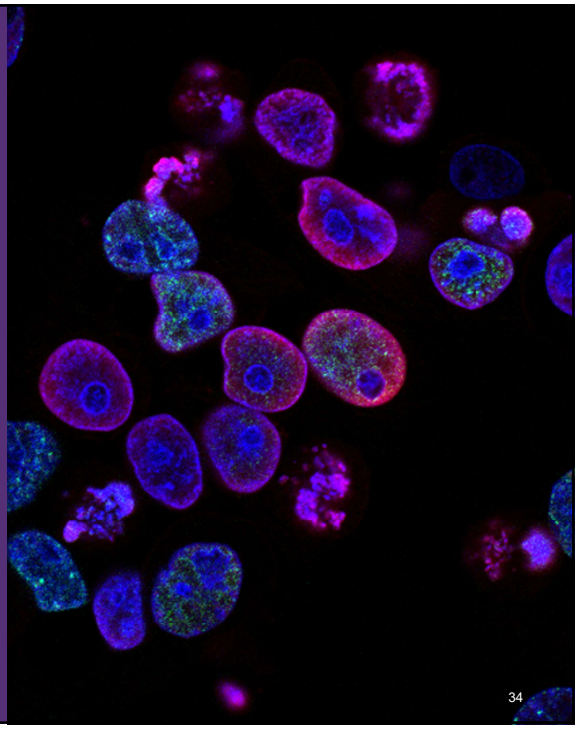
Billing routine services to CMS

Medical Services Coverage Decisions That Relate to Health Care Technology: investigational device billing, 42 CFR 405.201-213 (1995, amended 2004, 2013, 2021)

NCD - Routine Costs in Clinical Trials (310.1): National Coverage Determination extending CMS coverage to non-device studies meeting requirements (2000, amended 2007)



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Federal awards: effort, patient care

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, Compensation – personal services, ***2 CFR 200.430***

NIH Grants Policy Statement, ***19 Research Patient Care Costs*** in particular, 19.4 Allowable Costs and 19.2 Definitions

See also Institutional resources on previous slide

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