

**RESEARCH COMPLIANCE 101:
WHY YOU SHOULD KNOW EVEN IF YOU
DON'T THINK YOU ARE DOING RESEARCH**

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Today's Topics/Agenda

1. Discuss emerging issues in research compliance
2. Explore how the structure of a health system impacts research compliance
3. Review suggestions on research compliance training to help manage risk



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Enforcement/Actions

• What agencies are concerned with research compliance and what are the issues? (just a selection!)

- Human Subject Protection
 - OHRP
 - FDA
 - NIH
- Clinical Research Billing
 - CMS
 - OIG
 - DOJ
 - State AG
- Federal Grants
 - NIH
 - OIG
 - DOJ

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Top 7 Issues
(not presented in order of importance)

1. Movement of clinical research into the community setting

- For many years, clinical research has been the domain of academic medical centers...not any more.
- Some estimates peg 40% of clinical research is performed at a community hospital or in independent physician practices

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Top 7 Issues
(not presented in order of importance)

2. Not knowing the studies conducted at your institution – and not knowing who the patients are

- It seems like a simple thing, but it can be quite complicated!
- Who knows? The physician.
- Consider developing a process to be informed of the patient's enrollment at the time of signing informed consent
 - CTMS, secure email, or fax notification

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Top 7 Issues
(not presented in order of importance)

3. Not knowing who got paid for what

- Items and services paid for by the sponsor cannot be billed to insurance
- Who are the parties to the clinical trial agreement?
- Who took the money? What is the money for?
- Is the hospital receiving money that must be paid to a physician?

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Top 7 Issues
(not presented in order of importance)

4. Stark Law issues lurking in the confusion of documents

- Is the hospital taking money which must be paid to a physician? (For example, professional fees for radiology services)
- A financial relationship between a hospital and a physician who refers Medicare patients to the hospital must meet a Stark exception (and Anti-kickback Statute compliance must also be considered)
- Is there a negotiated rate for the physician's charges?

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Top 7 Issues
(not presented in order of importance)

5. Abiding by the financial discussion in the research informed consent

- Anything promised free in the research informed consent cannot be billed to insurance
- The informed consent must be written at a 6th to 8th grade reading level – it is interpreted from the perspective of the patient
- What is being promised free in the informed consent? Is there a system to manage this information?

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Top 7 Issues
(not presented in order of importance)

6. Not having a process to review research-related claims before sending to third-party payors

- Services which cannot be billed to insurance must have their charges directed to the study
 - There must be a process to:
 - A. Bring all the information together about the study to know which services can be billed to insurance and which can't ("Coverage Analysis")
 - B. Review claims against the Coverage Analysis
- The information in a Coverage Analysis should be coordinated between the hospital and the physician

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Top 7 Issues

(not presented in order of importance)

7. Auditing your IRB

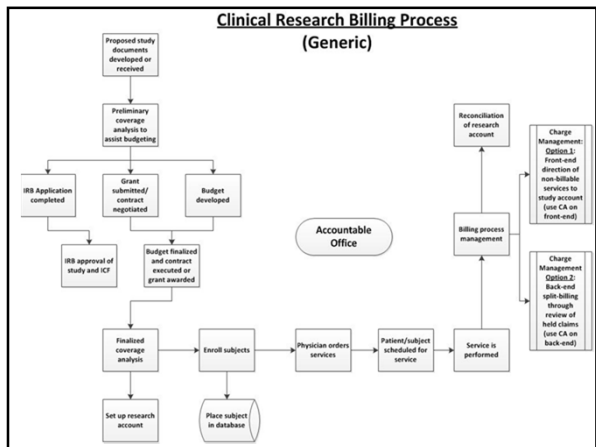
- Do you know who your IRB is?
- An institution can outsource the IRB function, but it cannot outsource the liability
- Compliance audits should occur for both internal IRBs and external IRBs
- Write into your contract with an external IRB the ability to conduct compliance audits

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Understand the legal structure of the research enterprise

- Who is taking the money?
- Who is signing the Clinical Trial Agreement?
- Where are the protocol services occurring?
- What IRB is approving the study?
- Has there been an administrative OK for the study?

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Summary of Clinical Research Billing Risks

1. Billing for services that are already paid by the sponsor (double billing)
2. Billing for services promised free in the informed consent
3. Billing for services that are for research-purposes only
4. Billing for services that are part of a non-qualifying clinical trial
5. Billing Medicare Advantage Plan when claim should be directed to Medicare Administrative Contractor ("MAC")
6. Not putting appropriate codes/identifiers on claims to Medicare and placing clinicaltrials.gov number on claim

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Common Rule Changes

- Published January 19, 2017
- Rule is effective January 19, 2018
- However....current regulatory freeze. Fate of Common Rule is unknown
- First significant changes in 30 years

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Common Rule Changes

- Proposed Rule would have expanded regulatory jurisdiction to all studies if the site took federal research money
 - Final Common Rule preserves status quo
- New requirements on information provided to subjects in informed consent forms
- Broad consent (consent to unspecified future research)
- New exempt categories but for some, light IRB oversight needed
- Lessens obligations to conduct continuing review for expedited review approved studies
- Central IRB for certain cooperate group research (effective 2020)

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Training challenges

- Principal Investigators – personally responsible for the research study
 - but may have a hard time getting on their schedule
- Study coordinators – the person who interacts the most with the subject, may negotiate the budget, and keeps track of everything for the investigator
 - but may have high turn-over in job, may have very little background in research
- Various administrative offices – need to interact with the research (e.g., medical records, billing office) but may have very little understanding of research
 - sometimes people are afraid of the “research language”

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Training ideas

- Have a cascade of research compliance education
 - Consider modules of subject-matter areas
 - Individuals may take all the modules or some of them based on job role
 - Have a module which introduces the person to clinical research
- Although the investigator may be interested in all the modules, the reality is you may need to have a slimmed down version pitched just for the investigators
- Don't forget senior leadership – they should understand the cost and complexity of research in order to make decisions about what level of commitment the organization will have for research

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Training ideas

- Modules for consideration:
 - Introduction to research terminology
 - How to start a research project and get it approved at the organization
 - Human Subject Protection
 - IRB review
 - Informed consent
 - Continuing review
 - Clinical Research Billing
 - Using databases (clinical trials management system)
 - Clinical trial agreements and budgeting
 - Managing research funds
 - What must be reported and when

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Questions?

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