

Research Compliance for the Hospital Compliance Officer

Presented by

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Objectives

- Understand the primary focus areas of a research compliance program
- Learn about the common compliance scenarios that occur in research
- Explore how deeply the hospital compliance program should dive into research– and when to consider specialized resources



Why Do You Need a Research Compliance Program?

- For the same reasons you need a general healthcare compliance program!
- Highly regulated area
- Researchers are themselves often confused about research rules and boundaries
- Hospitals were not designed to support research. Often the research support services are struggling to catch up to the research itself



Who Regulates Research?

- Office of Human Research Protections (OHRP)
- Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- Office for Research Integrity (ORI)
- Office of Management and Budget (OMB)
- Office of the Inspector General (OIG)
- Centers for Medicare & Medicaid Services (CMS)
- US Department of Agriculture (USDA)
- Office of Laboratory Animal Welfare (OLAW)
- Office of Civil Rights (OCR)
- State and local laws



What is Research?

- Defined in several different ways
- OHRP:
 - A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge



What is Research?

- Defined in several different ways
- FDA:
 - Clinical investigation: means any experiment that involves a test article and one or more human subjects, and that EITHER is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act
 - **OR** is not subject to requirements for prior submission to the Food and Drug Administration under these sections, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit



What is NOT Research?

- Quality Improvement Activities
- Implementation of new SOC processes
- Case Study or Case Series

- The Publication Myth
 - Just because you intend to publish or present what you have done, does not mean it is research (QI work, case study, etc.)



Common Research Compliance Topics



Human Subject Protection

- Research involving human subjects requires Institutional Review Board (IRB) review and approval **PRIOR** to initiation of the study
- What is a human subject?
 - A living individual about whom an investigator conducting research:
 - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; or
 - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens



Human Subject Protection: Informed Consent

- Informed consent should be sought from each subject unless waived by the IRB. Informed consent is required to be: informed, understood and voluntary.
- OHRP and FDA regulations contain a list of requirements for informed consent.
- Informed consent is a process, not a document. It's not enough to give someone the consent form and get their signature



Human Subject Protection: Requirements for IRB Approval

- The IRB must consider the approval criteria found at 45 CFR 46.111 and 21 CFR 56.111, commonly referred to as “the 111 criteria.”
- Consideration of additional findings that need to be made
 - Device determinations
 - Vulnerable populations



Conflict of Interest

- 42 CFR Part 50 Subpart F- *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought*
- Establishes standards to be followed by institutions that apply for or receive research funding from PHS Awarding Components
- Who is covered? Institution, Investigator, Subrecipient



Conflict of Interest

Institutional Requirements are Numerous...

- Institution is required to have a policy and inform investigators of their obligation to disclose
- Must solicit and review disclosures from investigators
- Must manage significant financial interests when deemed necessary
- Must report when required
- Must ensure subrecipients follow the regulation
- Certifications on certain funding applications



Conflict of Interest

- Consider how this is being managed at your institution
- Additional challenges include:
 - Obtaining timely disclosures
 - Ensuring consistency in management plans for your researchers
 - Mitigating researcher pushback when their role in the study is restricted by a management plan
 - Coordination with your general COI management



Clinical Research Billing

- Identification of services that can be billed to insurance
 - Medicare Coverage Analysis
 - Study calendar, budget
- Process to ensure you aren't billing services to insurance that were promised free in the informed consent document or that have a promised payer in the study contract



Clinical Research Billing

- Don't bill for things the sponsor of the study already paid for!
- Specific coding requirements
 - Z00.6
 - Condition code 30
 - NCT number
 - Required modifiers (Q1/Q0)

THIS IS A MANUAL PROCESS!



HIPAA and Research

- Research agreements need to account for privacy protections
 - Do you need a BAA? DUA? What type of data are you agreeing to provide to sponsors/collaborators/funders?
- **Clinical access to health information does not mean an investigator can use that access for research purposes**
- Research access and use of PHI is not covered as part of treatment, payment and operations



HIPAA and Research

- Generally, the Privacy rule requires a written, signed permission (Authorization) before the covered entity can use or disclose the individual's PHI for research purposes
- One way a covered entity can use or disclose PHI without an Authorization for research is by obtaining a waiver of the Authorization requirement by an IRB or Privacy Board
- Do you have a privacy board? Have you deferred this function to your IRB?



HIPAA and Research

Privacy Board vs. IRB

What is a privacy board?

- A review Body that may be established to act upon requests for a waiver or an alteration of the HIPAA Authorization requirement under the Privacy Rule for uses and disclosures of PHI for a particular research study
- Privacy Boards do not exercise any other powers or authority granted to IRBs related to research involving human subjects



HIPAA and Research

What is the IRB's role with respect to HIPAA?

- IRB's role under the Privacy Rule is limited to acting on requests for a waiver or an alteration of the Privacy Rule's Authorization requirement
- IRBs are not required to approve Authorizations, even stand-alone authorizations
- IRBs are not required to review uses and disclosures of an individual's PHI that are made with an individual's Authorization



HIPAA Waiver Criteria

- PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on at least the presence of
 - (1) an adequate plan presented to the IRB to protect PHI identifiers from improper use and disclosure;
 - (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification of retraining the identifiers or if retention is otherwise required by law; and
 - (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule



HIPAA Waiver Criteria (cont.)

- The research could not practicably be conducted without the requested waiver or alteration
- The research could no practicably be conducted without access to and use of the PHI



Other HIPAA Considerations

- IRBs/privacy boards may also grant an alteration of the HIPAA authorization
- Researchers may access PHI without an authorization or a waiver as long as it is for a purpose that is *preparatory to research*
 - Preparing a protocol, developing a research hypothesis, identifying potential subjects
 - PHI cannot leave the covered entity



Research Misconduct

- Office of Research Integrity (DHHS) regulations found at 42 CFR Parts 50 and 93 define research misconduct as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results”
- Regulation lays out the requirements for the process following an allegation of scientific misconduct



Research Misconduct

- Any institution that receives PHS funding must (1) have policies and procedures in place for investigating and reporting allegations of scientific misconduct and (2) file an annual assurance with ORI
- You should have a designated Research Integrity Officer (RIO)

- Even if you do not receive PHS funding, if you do research, you should have a policy on how your institution handles allegations of research misconduct



FDA Regulations

- Certain studies may involve interventions or products that are subject to FDA regulations.
 - Consider whether the research involves a drug that requires an investigational new drug application (IND)
 - Consider whether the research involves a device that requires an investigational device exemption (IDE)
- Is your research pharmacy complying with FDA regulations? Does it sit outside of your facility's primary pharmacy?



The Conduct of Research and Compliance with Good Clinical Practice Standards (GCP)

- Good Clinical Practice (GCP) are international quality standards for clinical research that address the design, conduct, monitoring, auditing, recording, analyses and reporting of clinical trials that provide assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected
- GCP standards address how to document key parts of the research study including informed consent, adverse event evaluation, and subject visits



The Conduct of Research and Compliance with Good Clinical Practice Standards (GCP)

- Institutions that conduct interventional research studies should have a quality assurance monitoring function, especially the institution has studies that do not have an external monitor
- If you have limited resources for quality assurance audits, focus on federally funded and federally regulated studies and studies
- QA audits can also be used to ensure researchers are following the IRB approved protocol, complying with COI management plans and fulfilling any reporting obligations for the study (FDA, clinicaltrials.gov, etc.)



Fiscal Compliance

- Effort Reporting
 - Process mandated by federal government to verify labor charges to, or cost shared on, sponsored projects are accurate, timely and reflect the actual level of work performed. Institutions are required to certify the effort spent by all employees whose salaries are charged directly to federal and federal flow through funds
- Sub recipient monitoring
 - Federal regulations require subrecipient monitoring. Examples of monitoring include:
 - Is subawardee's work progressing according to schedule?
 - Are funds being spent according to budget and project timelines?
 - Do invoices reflect allowable and reasonable costs?



Research Compliance in the Clinical Setting: Case Examples

A physician contacts your IRB office and says that he has conducted an exempt review of patient data and written a manuscript that he is submitting for publication. The journal requires proof of IRB approval and he is now seeking it. The IRB office refers the matter to compliance.

What research compliance issues might this implicate?



Research Compliance in the Clinical Setting

Case Examples

A member of study team contacts the compliance office to report that the Principal Investigator of the study has been manipulating lab values to make otherwise ineligible subjects eligible for the research study. The study team member also reports that the Principal Investigator has implied that he worries that the research sponsor will stop hiring him for consulting work if the study does not have high enrollment numbers.

What research compliance issues might this implicate?



Research Compliance in the Clinical Setting:

Case Examples

The compliance office is notified that there is an ongoing research study involving a surgical procedure where the investigator is removing tissue for pathology testing as part of the research study. The tissue removal and testing is not in the IRB approved protocol and is not in the consent form.

What research compliance issues might this implicate?



When Do You Need a Specialized Resource?

- Do you have an Institutional Review Board?
- What types of research are occurring at your facility?
- Are you billing for procedures in research studies?
- What controls do you have in place to address research billing requirements?
- Do you have policies in place related to the initiation and conduct of research?
- Are you receiving federal funds for research?



Questions??

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