Research Compliance for the Healthcare Compliance and Privacy Officer

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Objectives

- Understand the main regulatory focus areas of a research compliance program
- Explore how a healthcare compliance program can incorporate research
- Learn about ways to resource and structure a research compliance program

What is Research?

Office for Human Research Protections (OHRP) Common Rule [45 CFR 46]: *A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge*

National Institutes of Health (NIH): *A systematic study directed toward fuller scientific knowledge or understanding of the subject studied*

Food & Drug Administration (FDA) provides a definition for clinical investigation: *any experiment that involves a test article and one or more human subjects…*

Versus non-Research

Examples:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, historical scholarship)
- Public health surveillance
- Limited Case Studies (based on institutional policies, but HIPAA requirements may still apply)
- Non-Human Subjects Research (determined by the IRB/policy)
- Quality improvement/operational processes

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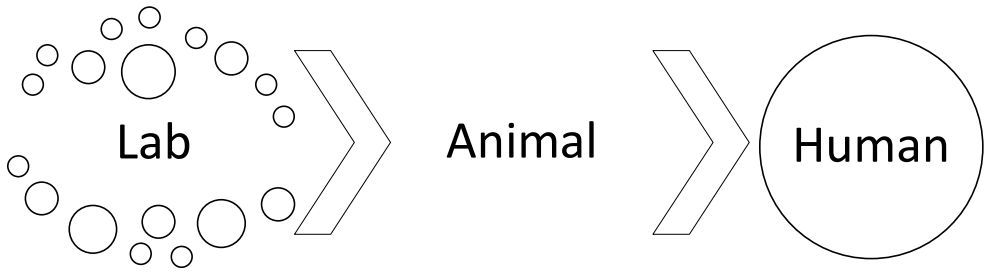
Research Life Cycle



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Research Challenges in Healthcare Environments

- ✓ High risk due to highly regulated environment layered on top of healthcare
- ✓ International and innovative activities
- ✓ Clinical care vs. research distinction
- ✓ Data & documentation centric – integrity and reproducibility are key

Innovation does not often fit neatly into regulations or established healthcare environments or systems

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The Value of a Research Compliance Program

- ✓ Ensures compliance with various regulatory requirements
- ✓ Reduces organizational risks and protects the integrity of the research
- ✓ Essential to program accreditation and federal assurances
- ✓ Provides structure for responding to agency investigations, inspections or audits
- ✓ Focuses on a unique and evolving area
- ✓ Creates a more comprehensive healthcare compliance program

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Regulatory Focus Areas of

Research Compliance

Regulatory Agencies Pertaining to Research Activities

Major Federal Agencies include:

- Office of Laboratory Animal Welfare (OLAW)
- US Department of Agriculture (USDA)
- Occupational Safety and Health Administration (OSHA)
- US Drug Enforcement Administration (DEA)
- Office of Research Integrity (ORI)
- National Institutes of Health (NIH)
- Office for Civil Rights (OCR)
- Food and Drug Administration (FDA)
- Office for Human Research Protections (OHRP)
- Centers for Medicare and Medicaid Services (CMS)
- Office of Management and Budget (OMB)
- Depart of Commerce – Bureau of Industry and Security (BIS)
- State Department – Directorate of Defense Trade Controls
- Department of the Treasury – Office of Foreign Assets Control (OFAC)

Other Federal agencies may have oversight depending on the research and funding

→ **State, local and international agencies**

Laboratory and Animal Research Compliance Focus Areas

- Research regulatory committee approval: Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), etc.
- Laboratory safety and security
- Controlled substances state license, DEA registration & diversion controls
- Start-ups leasing lab space, conflicts of interest and commitment (faculty/students)
- Data integrity/reproducibility/research misconduct
- Grants & fiscal compliance
- International activities (e.g., export controls, visitors, screening, foreign assurance, etc.)
- Responding to state and federal agency inspections, audits and investigations

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Animal Welfare and the IACUC

Federally funded institutions that use laboratory animals for research require an IACUC:

> Committee required by Animal Welfare Act (AWA) and the Public Health Service Policy on Humane Care and Use of Laboratory Animals

> Has the authority to approve, require modifications in, or disapprove research. The Committee conducts evaluations of the institution's laboratory animal care and use program, including inspections of facilities that are required by law to assure the ethical treatment and use of animals in research activities

Compliance:

> IACUCs should have policies to investigate and report non-compliance

> Institutions should implement Post-Approval Monitoring and report non-compliance to the Office of Laboratory Animal Welfare (OLAW) – Division of Compliance Oversight

> USDA conducts AWA inspections at research facilities involving regulated animals & state level inspectors inspect research facilities with licenses

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Human Subjects Research Compliance Focus Areas

- Research regulatory committee approval: Institutional Review Board (IRB), Institutional Biosafety Committee, Radioactive Drug Research Committee, etc.
- Research subject protections: rights, safety and welfare
- Privacy & security – state, federal and international laws and regulations (HIPAA, GDPR, etc.)
- Data integrity/reproducibility/research misconduct
- Innovations, conflicts of interest and commitment
- FDA regulated products, Investigational New Drug (IND) and Investigational Device Exemption (IDE), use of controlled substances/marijuana-derived products
- Grants/contracts, fiscal/clinical research billing compliance
- International activities (e.g., export controls, screening, etc.)
- Responding to state and federal agency inspections, audits and investigations

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Human Subjects Protections and the IRB

> Human Subjects Research (HSR) is regulated through the Federal Policy for the Protection of Human Subjects (via recently revised Common Rule), FDA regulations for FDA regulated research & state laws

> HSR = Research involving a human subject or a living individual about whom an investigator conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

> Before initiating HSR, the project requires IRB review and approval, including review of consent forms (if used), COI, and ensuring regulatory requirements [45 CFR 46 111 and 21 CFR 56.111] are met

Focus Area: Increased use of external IRBs

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Human Subjects Protections and the IRB

Institutions that conduct HSR require an IRB (internal or external):

> Ethics review committee required by Federal Regulations [45CFR46] and FDA regulations [21CFR50] that reviews and monitors biomedical and behavioral research involving human subjects

> Has the authority to approve, require modifications in, or disapprove research. The purpose of IRB review is to ensure protection of the rights, safety and welfare of human subjects of research

Compliance:

> Human Research Protection Programs (HRPPs) should have policies to investigate and report non-compliance; Federal Wide Assurance (FWA) for federally funded research

> Institutions should implement a Quality Assurance program & report unanticipated problems and serious non-compliance to the Office for Human Research Protections (OHRP) & FDA (if app) → investigates noncompliance allegations

> FDA conducts inspections of IRBs and clinical investigators at research institutions involving FDA regulated clinical research

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OHRP Compliance Letters

Image from: https://www.hhs.gov/ohrp/compliance-and-reporting/determination-letters/index.html

Common Scenarios:

- Not-for cause evaluations by OHRP
- Allegations of non-compliance:
  - Not reporting unanticipated problems involving risks to subjects or others to the IRB and OHRP
  - Consent issues related to: process and documentation; responsibility of costs
  - Protocol violations, subject eligibility, inadequate documentation of adverse events and safety monitoring
  - Lack of IRB review & written procedures

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HIPAA & Privacy Boards in Research

- A covered entity (CE) can use or disclose the individual's PHI for research purposes only through:
  - ✓ Signed HIPAA authorization from the research subject
  - ✓ Waivers/alteration of HIPAA authorization issued by the Privacy Board
- Privacy Board (usually IRB) acts upon requests per Privacy Rule requirements and must document waiver or alteration determinations & approval
- Usually the HIPAA authorization is attached to OR combined with the research consent form (requiring review by the IRB)

Reviews Preparatory to Research

- Allows CEs to use or disclose PHI for preparing a protocol, feasibility, identifying prospective research participants
- Does NOT permit researcher to remove the PHI from the CE

HIPAA & HSR Regulations do not apply to research using de-identified information

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Other Privacy Considerations

- ✓ Using and disclosing PHI for research purposes is NOT considered Treatment, Payment or Operations (TPO)
- ✓ Understand your arrangements and impact on access, use & disclosure of PHI for research: Hybrid Entity, Organized Health Care Arrangement (OHCA), Business Associates, Collaborators, Sponsors
- ✓ Minimum necessary standard applies to research
- ✓ Other types of agreements may be needed: Data Use Agreement (DUA) for limited data sets
  - ✓ Accounting of PHI disclosures <u>without</u> the individual's authorization is required except for DUAs
- ✓ Be mindful of state laws and international regulations like the General Data Protection Regulation (GDPR)

Remember that privacy and security often go hand-in-hand

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OCR Settlements & Cases

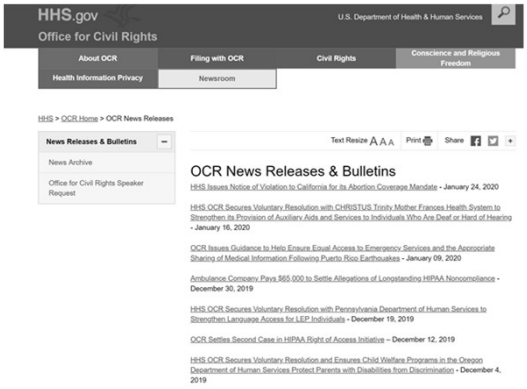

Image from: https://www.hhs.gov/ocr/newsroom/index.html

Cases to pay attention to:

- Loss or theft of unencrypted mobile devices: laptops and flash drives
- Social media disclosure of PHI
- Server issues that allowed uncontrolled access to PHI via the internet
- Phishing/malware incident leading to breaches
- Improper implementation of hybrid entity designation
- Failing to secure a business associate agreement with vendors with access to PHI

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FDA Regulated Research & Standards

U.S. FOOD & DRUG ADMINISTRATION

Image from www.fda.gov

Clinical investigations involving FDA regulated test article (drugs, biologics, & devices) and human subjects:

- Investigational new drug application (IND) [21 CFR 312]
  - ✓ Not-yet approved/marketed OR approved, but new indication for use/significant labeling changes
  - ✓ Marijuana-derived and DEA schedule I products
- Investigational device exemption (IDE) [21 CFR 812]
  - ✓ Not-yet approved/marketed OR new intended uses of marketed devices
  - ✓ Significant Risk vs. Non-Significant Risk Devices
- Does not include off-label use for treatment purposes
- Expanded Access/Compassionate Use involving investigational products for treatment purposes require IRB and FDA approvals

ICH E6 (R2) Good Clinical Practice (GCP) quality standards in the design, conduct monitoring, auditing, recording, analyses and reporting of research

Focus areas: Sponsor-investigators, Clinicaltrials.gov requirements, FDA inspection preparation, management and response: IRBs & investigators

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FDA Warning Letters

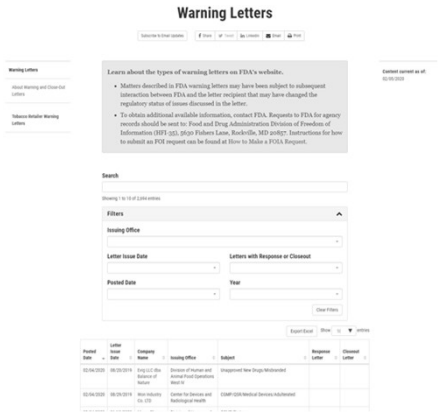

Image from: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters

Common Clinical Investigator Findings:

- Failed to ensure that the investigation was conducted according to the investigational plan [21 CFR 312.60]
- Failed to maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation [21 CFR 312.62(b)]

Common IRB Findings:

- Failed to prepare, maintain, and follow required written procedures governing the functions and operations of the IRB [21 CFR 56.108(a), 21 CFR 56.108(b), and 21 CFR 56.115(a)(6)]
- Failed to prepare and maintain adequate documentation of IRB activities, including minutes of IRB meetings [21 CFR 56.115(a)(2)]

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Research Integrity

U.S. Department of Health & Human Services
THE OFFICE OF RESEARCH INTEGRITY

Image from www.ori.hhs.gov

Federally funded research - annual assurance filed with ORI, policies and procedures and designated Research Integrity Officer (RIO)

Research Misconduct [42 CFR Part 93]:

✓Falsification = manipulating research materials, equipment, or processes, or changing/omitting data/results such that the research is not accurately represented in the research record

✓Fabrication = making up data/results and recording/reporting them

✓Plagiarism = appropriation of another person's ideas, processes, results or words without giving appropriate credit

…in proposing, performing or reviewing research or reporting results

Conflict of Interest

- PHS funded research [42 CFR 50, Subpart F]: financial COI regulations to promote objectivity in research
- FDA [21 CFR 54]: financial disclosure by clinical investigators
- Various types of COI in research to be disclosed, reviewed and managed including individual and institutional

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Research Integrity Settlements & Cases

Research Misconduct

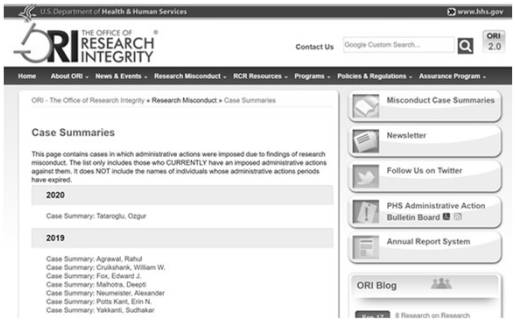

Image from: https://ori.hhs.gov/case_summary

Common or Interesting Findings:

- Falsifying or fabricating data in papers and grant applications & progress reports
- Manipulating or falsifying data, images, graphs
- Selectively including or omitting data points from analysis
- Using own blood samples and representing them to be from study subjects

False Claims Act liability

Note that a majority of ORI cases occurred in non-clinical research projects

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Fiscal Management & Compliance

Federal Grants Compliance – OMB Uniform Guidance [2 CFR 200]

- Pre & post award management including time and effort, subrecipient monitoring, procurement standards, cost principles, reporting obligations, audit, etc.
- Emphasis is on internal controls and responsible stewardship of sponsored funds

Clinical Research Billing – CMS Rules

- Dependent on clinical trial agreement, coverage analysis and billing grids/budgets
- Involves splitting services paid for by the sponsor and insurance, including government payors (e.g., Medicare, Medicaid), Medicare Advantage
- Qualifying Clinical Trials need to meet criteria under the Medicare Clinical Trial Policy
- Billing and coding rules: Z00.6, Modifiers (Q1, Q0), Condition Code 30, diagnosis code V70.7, and NCT#, MR documentation

False Claims Act liability

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Explore How a Healthcare Compliance Program can Incorporate Research

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Integrating Research Compliance

- Invest in resources & compliance staff with experience, knowledge and expertise to effectively cover all research areas
- Don't embed within operations
- Create a seat at the table with direct reporting to the board
- Ensure regular communication with the Chief Compliance Officer & Research Leadership
- Liaise between research and corporate areas including legal and risk management
- Establish policies that establish authority, roles and responsibilities

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Compliance Crossover Areas

- ✓Conflict of Interest (Individual and Institutional)
- ✓Privacy & Security
- ✓Research Billing
- ✓Global & International Activities
- ✓Policies & Procedures
- ✓System level committees (e.g., compliance, IT security, privacy, etc.)
- ✓Education and training

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Ways to Resource and Structure a Research Compliance Program

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Understand and Evaluate Your Organization's Research Portfolio & Infrastructure

Research size and scope

- Lab, animal and/or human
- Funding types & amount (e.g., internal, state, federal, private/industry)
- Location/setting of research studies
  - Local, national, international
  - Outpatient, inpatient, community based, academic

Other activities or programs

- Manufacturers, FDA related risks
- Start-ups, JVs, innovations, etc.
- Educational or industry partnerships

Infrastructure

- Research administration, research support offices, regulatory committees/offices, legal
- Reporting and management of compliance and regulatory issues in research
- Electronic systems, data uses & flows

Evaluation

- Compliance programs & staff from other similar organizations
- National surveys and speaking to colleagues

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Perform a Research Risk Assessment

> Interview stakeholders (e.g., investigators, research staff, administrators, research support staff and organizational leaders)

> How compliant is the organization?

- FDA warning letters, ORI & history of non-compliance (e.g., OHRP and OLAW reports)
- Audits results

> Evaluate regulatory agency priority areas and concerns

> Determine need and high risk areas to inform resources and budget development

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Don't Forget About the Culture

> Finding staff with the right experience and background is important

> Building compliance programs in various areas may take time → think about a phased approach

> Establishing relationships and trust also takes time

> Boundaries are important; ensure independence within compliance function

> Your function and role must be supported

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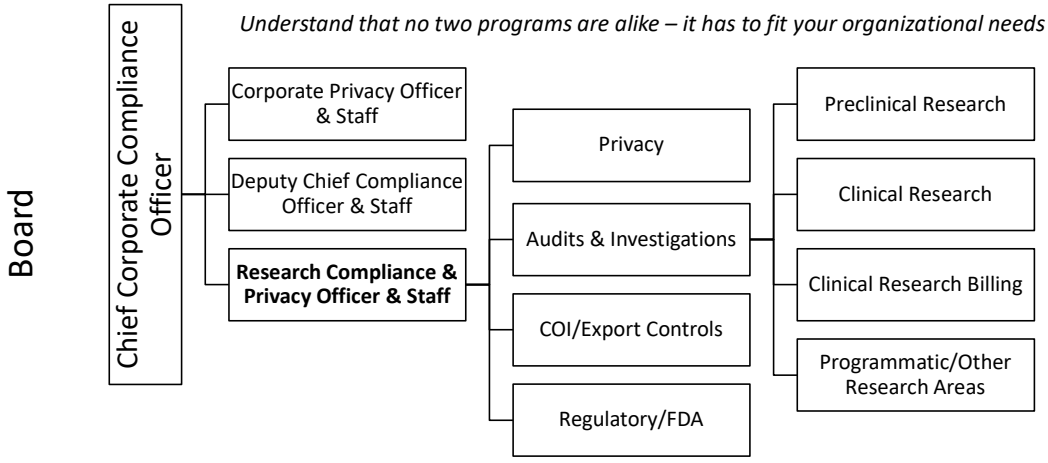
Example of Our Org Structure

Understand that no two programs are alike – it has to fit your organizational needs



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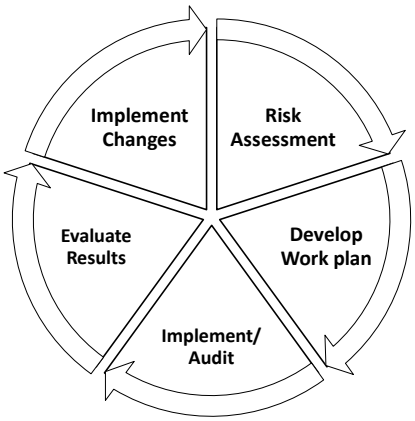
Compliance Work Plan & Program Development

- Based on internal and external risk assessment
- Covers high risk and priority areas
- Incorporate into the annual Corporate Compliance work plan
- Present to the board for approval & disseminate to leadership
- Implement the work plan & evaluate results
- Make adjustments to the program and repeat cycle



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Final Takeaways

> Regularly evaluate compliance and make adjustments tailored to changes in the organization's research program

> Network with other colleagues who can act as a resource and share insights about their programs

> Research compliance will continue to become more complex, but if your organization has ongoing research the investment is worth it!

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Thank You – Questions?

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