Southcentral Foundation
Program Highlights

2017 Alaska Native Health Research Conference

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65,000 voices
Why Research Compliance?

- Highly regulated
- Multiple Oversight Agencies (NIH, FDA, OHRP, ORI, OCR)
- Compliance failures pose a high risk of reputational and financial harm to both participating facilities and the researcher
Compliance Department’s Role

- Member of the Research Oversight Committee
- Review all research proposals, abstracts, manuscripts with focus on compliance and privacy protections
- Provide consultation services to help researchers and the research department comply with research rules and privacy requirements
- Establishes expectations and accountability
- Helps ensures research integrity and high quality data
Primary Compliance Risks

• Scientific misconduct
• Complex billing requirements
• Conflicts of interest
• Privacy protections
Scientific Misconduct

Fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the research and/or scientific community for proposing, conducting, or reporting research.

- Policies and procedures help to guard against misconduct.
Managing Complex Billing Requirements

- Billing for Services:
  - That are already paid by the sponsor (double billing)
  - Designated “free” in the informed consent
  - That are for research services only
  - That are part of a non-qualifying clinical trial
Perception is Reality
Conflict of Interest (COI)

Circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest

- A situation when an individual’s personal interest; or concerns are inconsistent with the best interests of an employer, a customer/client, or
- The individual's or organization’s business, financial or other considerations have the potential to compromise or bias professional judgement and objectivity
Disclosures

- Federal Regulations require disclosure of potential conflicts of interest
- Establish guidelines for managing conflicts
# Examples of Required Disclosures

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<th>Purpose</th>
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| COI/COC        | Employees      | • External interests  
• Relationships                                                                | Annual    | • COIs related to clinical, business, other activities  
• Commitment                                                                |
| Research       | Investigators   | • SFIs  
• Other specific thresholds/criteria of interests                             | Transactional | COIs related to research activities                                                                 |
| Committee/Group| Members        | • External interests  
• Relationships                                                                | Transactional | COIs related to specific defined business/other activities                                                                 |
| Institutional  | • Board  
• Senior officials | • External interests  
• Relationships  
• Holdings of the institution                                                   | Annual    | COIs related to organizational responsibilities and oversight                                                                 |
Effective means of identifying and managing conflicts are an important element in successfully achieving the goals of research. These strategies typically focus on the investigator and rely upon disclosure, which has substantial limitations.

• The risk that an individual’s external financial interests or relationships may bias or compromise – or have the appearance of biasing or compromising –

• an individual’s judgment, objectivity, or decision-making in clinical, research, and other activities.
Why is management of COI’s Important?

The relation and impact - even potential or perceived relation or impact - of external interests on research integrity and sound clinical judgment needs to be assessed, and any actual or perceived impacts mitigated.
Management of COI

- COI management strategies
  - Disclosure (to teams, research subjects, presentations and publications, etc.)
  - Reduced role in activity (recusal from certain activities, etc.)
  - Independent monitoring (of activities, data, etc.)
  - Elimination of interest causing conflict (divesture, etc.)
Privacy Protections

- HIPAA Privacy Rule
- Common Rule
- Food and Drug Administration (FDA)
Common Rule vs. Privacy Rule

Disclosure WITHOUT Customer-owner Authorization

- **Common Rule**
  - IRB Review – 4 Waiver Criteria Options
  - Minimal Risk
  - Preparatory to Research
  - Research on decedents
  - Limited Data Sets

- **Privacy Rule**
  - IRB/Privacy Board Review – 3 Waiver Criteria/Options
  - Preparatory to Research
  - Research on decedents
  - Limited Data Sets
Waiver of Authorization

- Only a Privacy Board or IRB can approve a waiver
- An IRB can approve however the facility may decline
Privacy Consultation for Waiver of Authorization

- Involves no more than minimal risk to the privacy of the individuals
- There is an adequate plan to protect the identifiers from improper use or disclosure
- There is an adequate plan to destroy the identifiers at the earliest opportunity
- There are adequate assurances the information will not be reused or disclosed
- The research could not practically be done without a waiver
- The research could not practically be conducted without access to the requested information
Safeguards

- Ensuring researchers are compliant with SCF research participation requirements
  - Meet SCF Background check requirements
  - Comply with privacy and security expectations
  - Establishing data use agreements and other agreements
Safeguards

- Evaluating the data requested to ensure:
  - Data is de-identified in a manner that protects the identities of participants
  - Establishing limited data set agreements;
  - Limiting access to minimum necessary and monitoring access;
  - Ensuring research data is transmitted securely and stored on secure (encrypted) computers and servers;
  - Ensuring participants are fully informed and consent
  - Evaluating waiver of authorization requests
Thank You!

Qagaasakung
Aleut

Mahsi'
Gwich’in Athabascan

Quyanaa
Alutiiq

Igamsiqanagghalek
Siberian Yupik

Awa'ahdah
Eyak

Háw'aa
Haida

Quyana
Yup’ik

T’oyaxsm
Tsimshian

Gunalchéesh
Tlingít

Tsin'aen
Ahtna Athabascan

Chin’an
Dena’ina Athabascan