How to Overcome the Challenges of Effectively and Legally Implementing Research in a Skilled Nursing Facility

HCCA Research Compliance Conference
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A Little Humor Before We Begin
Where are we going?

**Part One**  
Introduction and Overview

**Part Two**  
Overview of  
Skilled Nursing Facility Compliance

**Part Three**  
Research Compliance Basics

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**Part Four**  
Unique Challenges of Research in  
Skilled Nursing Facilities

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How to Compliantly do Research in  
Skilled Nursing Facilities

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Application
What is Healthcare Compliance

Healthcare Compliance – The ongoing process of meeting or exceeding the legal, ethical, and professional standards to a particular healthcare organization or provider. (Kusserow)

1. A culture of compliance promotes prevention, detection and resolution of instances of conduct that do not conform to government laws, public and private payor healthcare program requirements, and ethical and business policies.

2. The biggest challenge for healthcare organizations and their compliance officers is to keep track of all of the requirements and regulations, which are extremely numerous.
What Does it Mean to be Compliant

1. Avoiding or minimizing liabilities, including legal or regulatory penalties and potential civil litigation.

2. Following applicable federal and state laws and regulations.

3. Not presenting false claims for payment.

4. Developing effective processes, policies, and procedures to define appropriate conduct, training the organization’s staff, and monitoring adherence to the processes, policies and procedures.

5. Having verifiable Metrics.

6. Identifying gaps in the program and taking action to correct them.
Part Two

Overview of Skilled Nursing Facility Compliance

1. Statutory Requirements
2. Requirements of Participation
3. Regulatory Guidance

Statutory Requirements

Patient Protection Affordable Care Act (Public Law 111-148)

1. Section 6102 Subtitle B Nursing Home Transparency and Improvement
   (42 USC 1320a-7j)

   a. Have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations.
Requirements of Participation

Compliance and Ethics Program (42 CFR 483.85)

Regulation requires implementation of 11 Items as follows:

1. Written compliance and ethics standards, policies and procedures;

2. Assignment of “high level” individual(s);

3. Sufficient resources and authority to individual(s) overseeing the program;

4. Documentation of Due Diligence;

5. Effective communication of program standards, policies and procedures;

6. Reasonable steps to achieve compliance with program’s standards, policies and procedures; standards, policies and procedures;
Requirements of Participation (Con’t)

Compliance and Ethics Program (42 CFR 483.85)

Regulation requires implementation of 11 Items as follows:

7. Consistent enforcement of the programs standards, policies and procedures;

8. Ensuring all “reasonable steps” are taken to “respond appropriately”;

9. Conduct annual and mandatory program training;

10. Designating a Compliance Officer; and

11. Designating a Compliance Liaison(s).
Regulatory Guidance

Office of Inspector Guidance


Part Three

Research Compliance Basics

1. Institutional Review Board

2. Informed Consent

3. Belmont Report
Institutional Review Board

1. What is it?
2. Why does it matter?
3. How to ensure compliance?

Informed Consent

1. Why does it matter?
2. How do you get it?
3. How to ensure compliance?
Belmont Report

1. What is it?
2. Why is it important?
3. How to ensure compliance?

Part Four

Unique Challenges of Research in Skilled Nursing Facilities

1. Informed Consent
2. Survey Items (Care Issues)
3. Time
4. Payment
5. Charting
Unique Challenges of Research in Skilled Nursing Facilities

Informed Consent

1. What is it?
2. Why is it challenging?
3. How do you get it?

Survey Items

1. What are risks?
2. How do you assess risks?
3. How do you protect against risks?
4. Do you need to decline?
Unique Challenges of Research in Skilled Nursing Facilities

**Time**

1. How much time will this take?
2. Do you have enough staff?
3. How will this effect care?

**Payment**

1. Is what is done that is billable?
2. Is research entity paying for service?
3. Is service part of the daily rate?
Unique Challenges of Research in Skilled Nursing Facilities

**Charting**

1. What needs to be charted?
2. Where does it need to be charted?
3. Who is doing the charting?

Part Five

How to Compliantly do Research in Skilled Nursing Facilities

1. Patient Care
2. Consent
3. Regulations
Part Six

Application

1. Metrics
2. Data
3. Tool

Tool Overview
Tool Overview

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SNF Research Compliance Assessment Framework
Measurement Research Compliance Assessment Dashboard
Measurement Institutional Review Board
Measurement Informed Consent
Measurement Belmont Report

Tool Overview

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Tool Overview

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Questions???

Everyone has a hand in Compliance

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