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LEGAL COUNSEL

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

HCCA Research Compliance Conference
Tuesday June 2, 2020

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A Little Humor Before We Begin

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Where are we going?

Part One
Introduction and Overview

Part Two
Overview of
Skilled Nursing Facility Compliance

Part Three
Research Compliance Basics

Where are we going?

Part Four
Unique Challenges of Research in
Skilled Nursing Facilities

Part Five
How to Compliantly do Research in
Skilled Nursing Facilities

Part Six
Application

Introduction

Introduction

1. Why are we here?
2. Why is it important?
3. What will I learn?

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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.

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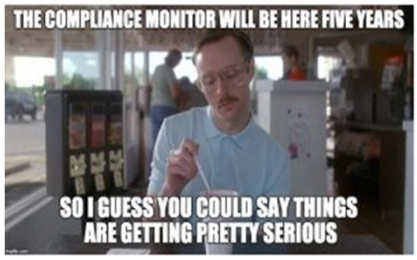
What Does it Mean to be Compliant

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.



What Does it Mean to be Compliant (Con't)

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;

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Requirements of Participation (Con't)

Compliance and Ethics Program (42 CFR 483.85)

Regulation requires implementation of 11 Items as follows:

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;

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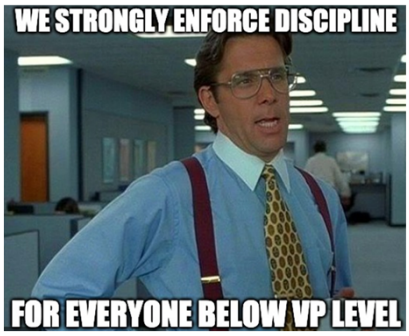
Requirements of Participation (Con't)

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";



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Requirements of Participation (Con't)

Compliance and Ethics Program (42 CFR 483.85)

Regulation requires implementation of 11 Items as follows:

9. Conduct annual and mandatory program training;

10. Designating a Compliance Officer; and

11. Designating a Compliance Liaison(s).

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Regulatory Guidance

Office of Inspector Guidance

1. Compliance Program Guidance for Nursing Facilities (65 Fed. Reg. 14289)

2. Supplemental Compliance Program Guidance for Nursing Facilities (73 Fed. Reg. 56832)

Part Three

Research Compliance Basics

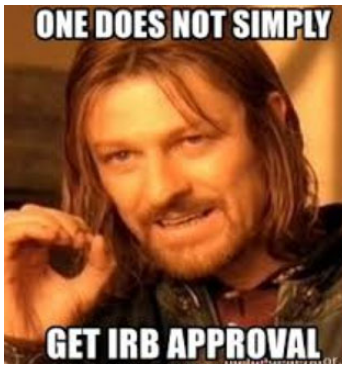
1. Institutional Review Board

2. Informed Consent

3. Belmont Report

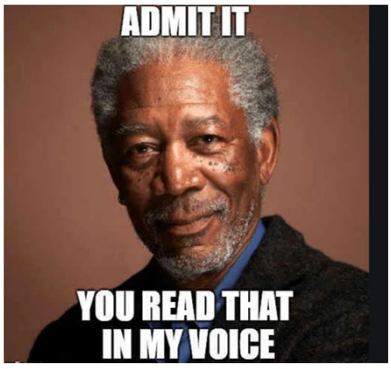
Institutional Review Board

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



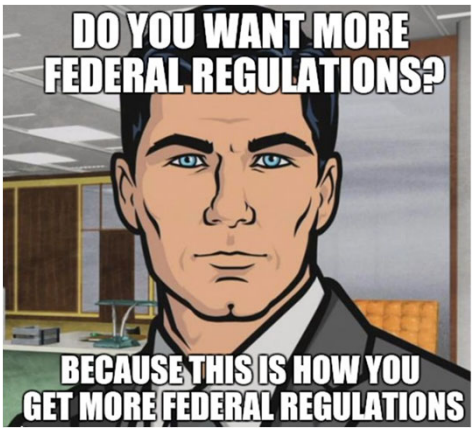
Informed Consent

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?



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Part Four

Unique Challenges of Research in Skilled Nursing Facilities

1. Informed Consent
2. Survey Items (Care Issues)
3. Time
4. Payment
5. Charting

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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?

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Unique Challenges of Research in Skilled Nursing Facilities

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?

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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?

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Unique Challenges of Research in Skilled Nursing Facilities

Payment

1. Is what is done that is billable?
2. Is research entity paying for service?
3. Is service part of the daily rate?

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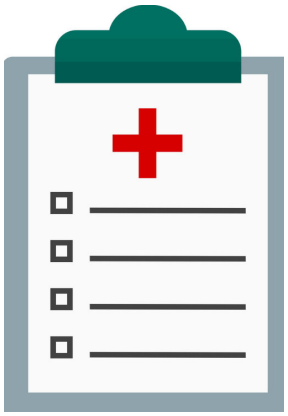
Unique Challenges of Research in Skilled Nursing Facilities

Charting

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



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Part Five

How to Compliantly do Research in Skilled Nursing Facilities

1. Patient Care
2. Consent
3. Regulations

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Part Six

Application

1. Metrics
2. Data
3. Tool

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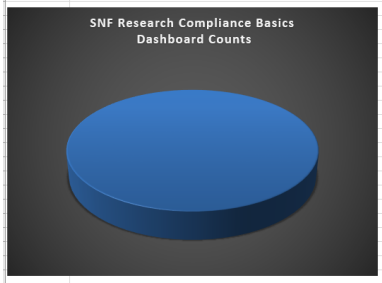
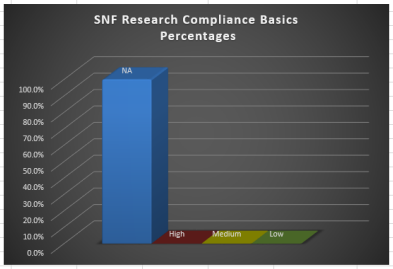
Tool Overview

Evaluated *Month Year* by *Your Name*

Each element has a Measurement (ME) section.
The Measurement section has a dashboard worksheet with sub-totals.

Legend	Description	Comment
NA	Not Applicable at this time	Doesn't pertain to us
Not	Not Implemented Yet	Not started or barely started
Partial	Partially Implemented	Well into it but more to do
Fully	Fully Implemented	Virtually all done





SNF Research Compliance Assessment Dashboard

Compliance Area	Compliance Description	NA at this time	Not	Partial	Fully	Total
1	Institutional Review Board	23	0	0	0	23
2	Informed Consent	33	0	0	0	33
3	Belmont Report	13	0	0	0	13
	Totals	**69**	**0**	**0**	**0**	69
	Percentages	100.0%	0.0%	0.0%	0.0%	100.0%

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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

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Tool Overview

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Measurement Dashboards

SNF Research Compliance Assessment Framework

Area One: Institutional Review Board

Category	Count	NA	Not	Partial	Fully
IRB Membership	6	6	0	0	0
IRB Functions and Operations	2	2	0	0	0
IRB Review of Research	5	5	0	0	0
Expedited Review	3	3	0	0	0
Criteria for IRB Approval of Research	2	2	0	0	0
Review by Institution	1	1	0	0	0
Suspension or Termination of IRB Approval of Research	1	1	0	0	0
Cooperative Research	1	1	0	0	0
IRB Records	2	2	0	0	0
Totals	23	23	0	0	0

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Tool Overview

TOC

			23	0	0	0	

SNF Research Compliance: Institutional Review Board

An IRB is a committee within a university or other organization receiving federal funds to conduct research that reviews research proposals. The IRB reviews the proposals before a project is submitted to a funding agency to determine if the research project follows the ethical principles and federal regulations for the protection of human subjects. The IRB has the authority to approve, disapprove or require modifications of these projects.

An IRB consists of at least five members of varying backgrounds. IRB members should have the professional experience to provide appropriate scientific and ethical review. An IRB must have at least one scientist member and at least one member whose primary concerns are nonscientific. Additionally, there must be one member who is not otherwise affiliated with the institution (a community representative). The IRB should strive for appropriate representation in gender and racial and cultural heritage as well.

In 1974, the Department of Health Education and Welfare promulgated the regulations on the Protection of Human Subjects that established the IRB. IRBs are administered on a federal level by the Office for Human Research Protections (OHRP), an office within the Department of Health and Human Services. OHRP assists IRBs in their work and receives and investigates claims of inappropriate research practices.

The institution that the IRB serves provides administrative support for its activities including designation of an individual within the institution to oversee research and IRB functions. The institution also files an "Assurance" with the federal government that describes the procedures and guidelines that the IRB must follow.

			Compliance Level				
Item#	Compliance Area	Action(s) to be Taken to Prove Effectiveness	NA at this time	Not	Partial	Fully	Comments
	IRB Membership:						
1.01	Membership Composition	• Are there at least five (5) members with varying backgrounds? • Is the IRB able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice? • If the IRB regularly reviews research that involves vulnerable categories of subjects (ie children, prisoners, pregnant women) is consideration given to the inclusion of one or more individuals who are knowledgable and experienced working with these subjects?	X				
1.02	Gender of Members	• Are there members of both genders on the IRB? • Does the IRB consist of members from multiple professions?	X				
1.03	Expertise of Members	• Is at least one member of the IRB primary concern in scientific areas? • Is at least one member of the IRB primary concern in non-scientific areas?	X				

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Questions???

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Everyone has a hand in Compliance

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