



# What Is Quality in Research?

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# Objectives

- Correlate regulatory and quality principles to your practice

# What is quality?

What does Quality mean to you?

# Quality Review

- “Quality is about meeting the needs and expectations of customers”<sup>1</sup>
- “The standard of something as measured against other things of a similar kind; the degree of excellence of something”.<sup>2</sup>

# The things we expect.....

- Every-day items
  - Toilet paper
  - Keyboard and mouse
  - Computer/laptop
  - Food
- Quality is Everywhere!

# Quality Aspects <sup>3</sup>

- Producing
- Checking
- Quality Control
- Quality Management
- Quality Assurance

# What is quality in Health Care?

# What does quality mean to you, the patient?

- The right care for every person every time

Centers for Medicare and Medicaid Services

# Six Characteristics of Health Care Quality <sup>4</sup>

- Safe
- Effective
- Person-centered
- Timely
- Efficient
- Equitable

# Quality in Clinical Research

- What does quality in clinical research mean?

# AN FDA Perspective <sup>5</sup>

- According to Jean Toth-Allen, Ph.D. Biophysicist- Office of Good Clinical Practice Office of the Commissioner May 14, 2012
  - Scientifically valid and ethically sound experimental design
  - Adequate protection of subjects rights, safety, and welfare
  - Qualified personnel
  - “Adequate” monitoring
  - Current, complete, and accurate data

# Regulations and Quality: staff qualifications and Training

Requirement: Select qualified investigators to conduct clinical research (21 CFR 312.50)

Quality:

Your site:

# Regulations and Quality: protocol and data

Requirement: Assure protocol & data requirements optimized (21 CFR 312.320 & 312.62)

Quality:

Your Site:

# Regulations and Quality: Informed Consent

Requirement: Patient informed consent (21 CFR 312.62)

Quality

Your Site

# Regulations and Quality: Monitoring

Requirement: Ensure adequate  
monitoring (21 CFR 312.50)

Quality:

Your site:

# Regulations and Quality: Compliance

Requirement: Ensure investigator compliance (21 CFR 312.50)

Quality:

Your Site:

# Quality in Clinical Research

- What does Quality in clinical research mean?

# Parting Thoughts:

- Do quality and regulations go hand-in-hand?
- Do the regulations guide us towards quality?
- What quality improvement opportunities are there at your institution?

# References

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- 2 – Google - Oxford Dictionaries - [http://www.oxforddictionaries.com/us/definition/american\\_english/quality](http://www.oxforddictionaries.com/us/definition/american_english/quality) (found 6/16/0214)
- 3 – Goggle – Wikipedia - [http://en.wikipedia.org/wiki/Quality\\_\(business\)](http://en.wikipedia.org/wiki/Quality_(business)) (found 6/17/2014)
- 4 – Google – The Health Foundation - <http://www.health.org.uk/about-us/what-is-quality/> (found 6/17/2014)

- 5- BUILDING QUALITY INTO CLINICAL TRIALS – AN FDA PERSPECTIVE by Jean Toth-Allen, Ph.D. Biophysicist- Office of Good Clinical Practice Office of the Commissioner  
May 14, 2012

<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM303954.pdf> (found 6/17/2014)

- 6 –NCQA: The Essential Guide to Health Care Quality (11/2009)