

# Implementing e-Consent for Clinical Trials

## Table of Contents

### Introduction

**Informed Consent and the E-Consent System..... 3**

IRB Approval..... 3

Obtaining Consent ..... 4

Focus on Education and Interaction..... 4

Initiating e-Consent for a Clinical Trial..... 8

Protection with e-Consent ..... 8

Recordkeeping and Storage..... 9

Revising Consent Forms and Re-consenting ..... 9

Monitoring and Auditing ..... 10

System Integrity ..... 11

**The e-Consent Process: A Case Study..... 13**

**Regulatory Compliance ..... 19**

HIPAA ..... 19

Electronic Signatures..... 20

What Is Coming Next ..... 21

**Appendices..... 22**

- A. 21 CFR Part 50 – Protection of Human Subjects
- B. Informed Consent Information Sheet (FDA draft guidance)
- C. Guidance for Sponsors, Investigators, and Institutional Review Boards: Questions and Answers on Informed Consent Elements, 21 CFR § 50.25(c)
- D. 21 CFR Part 11 – Electronic Records; Electronic Signatures
- E. Guidance for Industry – Part 11, Electronic Records; Electronic Signatures – Scope and Application
- F. Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers
- G. Guidance for Industry: Electronic Source Data in Clinical Investigations
- H. EU GMP Guide Annex 11: Computerised Systems