



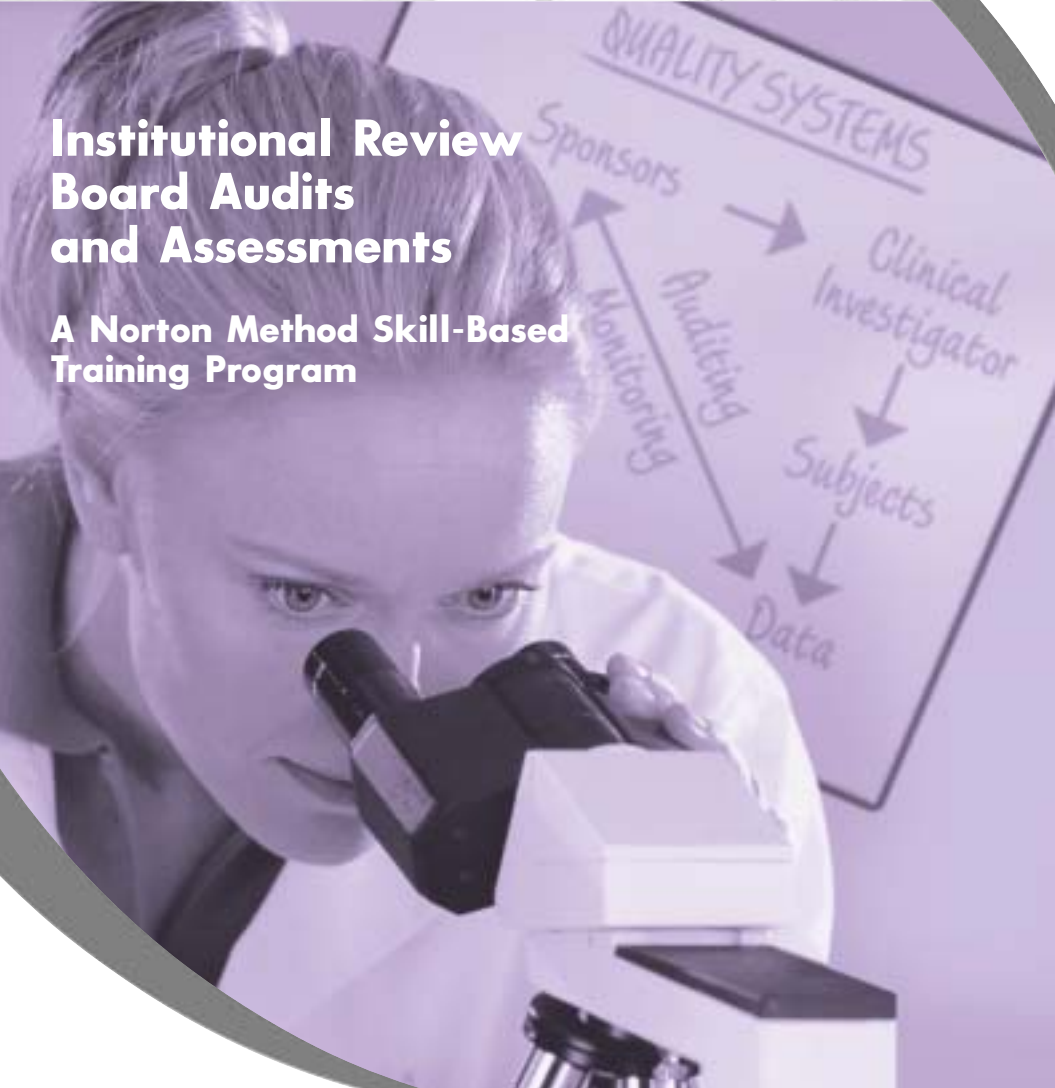
Norton Audits, Inc.

*Defining and Driving Clinical Research Excellence*



# Institutional Review Board Audits and Assessments

**A Norton Method Skill-Based Training Program**





**S**ince 1999, Norton Audits, Inc. (NAI) has been an expert resource for achieving clinical research excellence through specialized training and compliance services. Our skill-based training philosophy allows us to deliver practical information that is anchored in regulatory law and guidelines and teach skills you'll utilize immediately within your organization.

## YOUR CLASS SPECIFICS

**Course Name** - Institutional Review Board Audits and Assessments: A Norton Method Skill-Based Training Program

**Course Number** - TC-06

**Class Length** - Two days

**Description** - Receive expert training from an award-winning former FDA investigator on implementing Institutional Review Board (IRB) regulations when performing assessments on the behalf of sponsors and Contract Research Organizations. Participants will learn how the FDA conducts Quality Systems Audits of IRBs, increase writing and case development skills and leave this program with a clear understanding of the Title 21 and Title 45 Code of Federal Regulations.

### **Class Agenda/Modules** -

- Laws Governing IRB Operations
- IRB Global Quality Systems
- Auditing and Assessment Tools and Techniques
- IRB Standard Operating Procedures
- Writing Skills and Case Development

### **Typical Class Attendee** -

- Sponsor Auditors
- Contract Research Organization Auditors
- Institutional Review Board Internal Auditors
- Food and Drug Administration Investigators
- Independent Consultant Auditors
- Compliance Auditors

**Auditing Level** - Advanced; Auditor position for five years, preferably with a four-year medical or science degree

## YOUR GENERAL CLASS INFORMATION

Classes include handouts, manuals, lunch and snacks and are usually limited to 15 students in order to maximize student-instructor interaction.

Class times are generally 8:00 a.m. to 5:00 p.m. Visit [www.nortonaudits.com](http://www.nortonaudits.com) for current class

schedules. Most courses are offered every three months.

Continuing Education Units (CEUs) are provided, and other educational hours may be available. Please call for more information.



## YOUR INSTRUCTORS



**Tamera Norton  
Smith,  
PhD, MT(ASCP),  
President,  
Senior Consultant**

- Seventeen years' experience in clinical research including auditing, monitoring and consulting
- More than 10 years of teaching experience
- Former award-winning FDA investigator
- Nationally recognized by the U.S. Department of Health and Human Services for her work in biologics and GMP fraud detection
- Currently active as an auditor, author and trainer throughout the pharmaceutical and medical device industries
- Selected to train the U.S. FDA's Center for Devices and Radiological Health Division, 2004



**Elizabeth Ronk  
Nelson,  
MPH, National  
Compliance Director,  
Senior Consultant**

- Seventeen years' experience in the medical and clinical research field
- Direct experience with all site-based functions of clinical research
- Extensive experience in investigating and pursuing suspect clinical data cases
- Worked professionally with industry and government legal representatives to pursue legal actions for severe noncompliance cases
- Currently active throughout the pharmaceutical and medical device industries as an auditor, investigator and trainer

### Student Comments

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- "This training will help us win more studies."
  - Study Coordinator, Clinical Research Site
- "Very knowledgeable on topic she presented. Energetic and kept group engaged well. Great presenter. Very informative and applicable to my every day job."
  - Clinical Research Associates from Aventis
- "Every time I have heard your presentations, you have given me new life."
  - Senior Clinical Research Associate, Novartis

## YOUR CLASS LOCATIONS AND SCHEDULES

We can set up on-site training for a dedicated group of employees or as part of your company's regional or annual meetings. We also hold classes at our primary training location in Columbia, South Carolina, at a convenient meeting center or in local hotel conference rooms. In addition, we can schedule training at

our satellite locations in Atlanta, Georgia; Charlotte, North Carolina; and Philadelphia, Pennsylvania, as needed.

Monthly class schedules for our Columbia, South Carolina, location can be found at [www.nortonaudits.com](http://www.nortonaudits.com).

## YOUR CONTACT INFORMATION

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