



master™  
**CONTROL**

GxP PROCESS MANAGEMENT SOFTWARE

Less Paper.  
Less Effort.  
Less Risk.

# White Paper:

Ensuring the Adequacy of the  
Informed Consent Process in  
GCP Regulated Environments

By Rochelle L. Goodson,  
Co-Director QRTI, [www.qrti.com](http://www.qrti.com)



Consenting of subjects prior to their enrollment in a clinical trial is one of the most fundamental and well established requirements of clinical research. Physicians and the study staff consider it a routine task, yet inadequate informed consent issues remain one of the most common deficiencies cited by monitors, auditors, and inspectors.

Although the Informed Consent Form (ICF) serves as the mechanism for obtaining a signed and dated document, the process itself must be appropriately administered and documented. The ICF should be used as a springboard for providing information to facilitate a potential subject's decision-making with regard to participating in a clinical research trial. In addition to answering the subject's questions, the process should enable the consenters to ascertain that a potential subject understands the content of the consent.

Perhaps the real challenge is an honest evaluation of whether or not the goal of obtaining the subject's dated signature on an ICF undermines the intent of the process, i.e., to assure the subjects' rights, safety, and welfare. Circumstances, such as a small study staff, non-clinically trained staff, an overly-committed Principal Investigator, and tight or overly ambitious enrollment deadlines, are among the most common situations that encourage poor consenting practices.

The best place to start when assessing the consent process is to determine if the staff delegated with the responsibility for consenting has the appropriate training, education, and qualification to conduct the consent discussion. Although some Sponsors or Institutional Review Boards may insist that a physician and/or Principal Investigator personally consent a subject, the FDA regulations and the ICH GCP Guideline do not require that an investigator (or physician) do so.

A Principal Investigator that delegates the responsibility to consent subjects has the obligation to consider the following elements:

- the complexity of the study;
- the detail of the informed consent document; and
- the staff (administering consent) has the commensurate clinical background to assure that each subject is adequately consented.

At sites conducting multiple trials, Site Personnel Logs often reflect a number of staff with the responsibility of consenting rather than specific delegation to the most

appropriate member(s) of the study team. A thorough review of the curricula vitae and subsequent interview with staff can ensure that this key responsibility is appropriately delegated.

Whether or not the Principal Investigator personally conducts the consent discussion, he/she is ultimately responsible for the administration and documentation of the informed consent process and held accountable for lapses in compliance to the consent regulation.

In addition to the initial consenting of a patient, the regulations require that subjects are apprised of any new information that emerges during a trial that could impact on a subject's willingness to continue their participation. Therefore, re-consenting of study subjects (due to an amendment to the study protocol or new information about the investigational product under study) is often provided by the administration of a revised consent. Even though the FDA regulations do not require that the re-consenting process is documented in the subject's case history, good clinical practice dictates that it should be noted. The ICH GCP Guideline explicitly suggests that the communication of new information is documented.

Finally, informed consent review permits the assessment of the documentation of the informed consent process which can also uncover evidence of inadequate consenting. Missing signatures, initials, or dates, signatures provided in pencil, errors made by subjects and left uncorrected, and missing pages, are among the most common, but do not represent a complete list of documentation deficiencies. Documentation of the consent process should include the following elements:

- the date and time that the consent was administered;
- the version of the consent administered;
- a note that ample time to read and consider the consent was provided;
- a statement that the subject was provided with the opportunity to ask questions;
- a statement that the subject did/did not acknowledge understanding;
- the consent was administered prior to the performance of any study-related procedures;
- the subject received a signed and dated copy of the consent.

In summary, ethical research requires the adequate implementation of the consent process. The cornerstone for assuring that subjects' rights, safety, and welfare are

protected is the use of an appropriately reviewed and IRB-approved consent form. Perhaps the adage “the end justifies the means” serves to remind us that obtaining the signature on a consent form can only be justified if the process itself has been adequately and ethically implemented.

*Disclaimer: This white paper was not written to endorse any GMP or MasterControl product and should not be credited as such.*

### **About QRTI**

The Quality Research Training Institute was established in 2003 to offer advanced training for clinical research professionals by clinical research professionals.

The public courses explore challenging clinical research topics by experienced colleagues and instructors. Course content and workshops are updated regularly to explore current and emerging topics and issues that impact or are relevant to clinical research.

In-house courses are customized to individual company training and clinical research education needs while maintaining confidential company information and issues. Our public courses can be brought in-house for convenience of attendees while eliminating the expenses incurred for travel and employee downtime.

Lecturers Rochelle Goodson and Phyllis Kent have over 50 years combined experience in the areas of monitoring, clinical and regulatory safety reporting, FDA inspections and GCP compliance auditing and consulting.



© 2008 Quality Research Training Institute



master™  
**CONTROL**

GxP PROCESS MANAGEMENT SOFTWARE

Less Paper.  
Less Effort.  
Less Risk.

## MasterControl Inc.

### USA

6322 S. 3000 E. Suite 110  
Salt Lake City, UT 84121

P. 800.825.9117

F. 801.942.7088

[www.mastercontrol.com](http://www.mastercontrol.com)

### Europe

7200 The Quorum  
Oxford Business Park North  
Garsington Road  
Oxford OX4 2JZ  
United Kingdom

P. +44 (0) 1865 481481

F. +44 (0) 1865 481482

[www.mastercontrolglobal.co.uk](http://www.mastercontrolglobal.co.uk)