

HOW DO YOU DO QA?

QA involves the early identification of problems or potential problems in protocol compliance. To do this, the monitor compares what was done with an enrolled participant against what the protocol states is supposed to be done.

Some basic things to verify include:

- Informed consent is properly obtained and documented
- Only participants who meet inclusion/exclusion criteria are involved in the study
- Study procedures are carried out as planned and scheduled in the protocol
- Explanations are provided when things don't go as planned
- Signatures and dates are provided by the appropriate staff
- Clear documentation of how study procedures were conducted is present

PROTOCOL VIOLATIONS

Despite our best efforts, sometimes problems arise during the course of a study, either through complexity of the study, scheduling conflicts, inexperience, or carelessness. When study procedures don't get followed, protocol violations occur.

QA monitors anticipate seeing some protocol violations regardless of best efforts. The key concerns, however, are that the violations are not fraudulent, are documented and reported, and that some corrective action is taken to prevent future occurrences.

Identification of protocol violations are not condemnations of anyone's worth or ability, and monitoring activities are not meant to be adversarial. The process can be instructive and helpful and is in the best interest of the research participants and the study data.

PUTTING IT ALL TOGETHER

QA is a required process that involves the entire research team in a collaborative effort. If study staff and the QA monitor work together, they can:

- Ensure participant safety
- Protect confidentiality
- Collect high quality data
- Remain in study compliance
- Conduct the best possible research at each CTN study site

Talk with your QA monitor to see what you can do to help conduct the best possible research at your site.

FOR MORE INFORMATION

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Further information on the Clinical Trials Network can be accessed through the NIDA website at www.drugabuse.gov

NIDA NATIONAL INSTITUTE
ON DRUG ABUSE

*National Drug Abuse Treatment
Clinical Trials
Network*

**Quality
Assurance
& You**

**A GUIDE TO
CONDUCTING HIGH
QUALITY RESEARCH
IN THE CTN**

NATIONAL INSTITUTES OF HEALTH
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

The Clinical Trials Network (CTN) adheres to Food and Drug Administration (FDA) Good Clinical Practice (GCP) standards for conducting pharmacological and behavioral research. These standards include following regulatory guidelines for the protection of human subjects; assessing safety and reporting adverse events; following guidelines for the collection, reporting and storage of study data; and continuous monitoring of protocol adherence.

To help meet those standards, Quality Assurance (QA) procedures are designed to ensure that the study is being conducted appropriately. This brochure is designed to help demystify the process and explain how QA can work for you.

QA: WHAT IT IS AND WHAT IT ISN'T

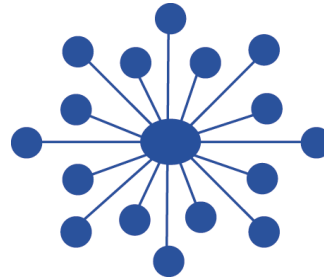
QA involves actions to ensure that the study is conducted as intended, that participant safety and confidentiality concerns are met, and that study data are of the highest quality.

QA is not something done as an afterthought — a plan should be developed before study enrollment begins. This applies to both the clinical site and to the data management center.

QA is not just the job of trained monitors. Everyone is involved in the QA process from the Node PI to the research assistant at the study site. Awareness of the responsibilities and expectations involved with QA will help ensure the highest quality CTN products now and in the future.

RAISING THE BAR

With multi-site clinical trials accounting for more research in the addictions treatment field (and all CTN research), strict FDA standards for study oversight are being used. These standards help to ensure the fidelity of the research being conducted.



WHEN DOES QA OCCUR?

Good QA for a study can require considerable time and effort, but the rewards include protection for participants and clean generalizable data.

QA occurs:

- During protocol development by creating a plan of action
- Before protocol initiation by providing training to study staff and monitors, and checklists for ensuring that all the pieces are in place
- At the start of the study by building a rapport between the study staff and the QA monitor and clarifying expectations
- During the study by maintaining good monitoring practices
- After the study has ended by maintaining follow-up procedures, data storage and confidentiality of participant information

THE AUDIT TRAIL

Clear documentation of how study procedures are implemented is necessary at all times. How the research is conducted at individual study sites is not the last step, it is just one of many steps.

Node personnel are responsible for regularly monitoring the study site, verifying study compliance, and reporting on the monitoring visits. In addition, independent monitoring contracted by NIDA occurs on a regular basis. If the study involves medications, the FDA may also be involved in study oversight.

As clinical trials become increasingly more complex, it becomes impossible to “remember what happened” or to “come back to it later” with respect to study procedures. Planned vacations, unplanned emergencies, and staff turnover make it necessary for documentation to be easily interpreted so that study procedures can continually move forward. Study staff need to plan ahead to make sure that documentation is complete and thorough. Remember, if it isn't written down, it didn't happen.

AVOIDING FRAUD

One of the benefits of performing regular QA activities is avoiding fraud or the appearance of impropriety. By having clear procedures and audit trails, your node and your sites help maintain high standards and avoid unnecessary shutdowns

While some problems and mistakes may occur during the course of a study, deliberately or systematically falsifying study documentation or data is completely unacceptable (and in some cases may be criminal).