CLINICAL RESEARCH COORDINATOR TESTIMONIAL:

"I found the QAIP Study Initiation Visit extremely helpful. Because I was new to research, I had a multitude of questions, and needed someone to help guide me through the entire research process.

During our meeting with the QAIP Coordinator, we were able to ask all the questions we had unanswered. She helped guide us in the proper direction for a safe study, and she has been continuously available to us as new questions have come up.

I would strongly recommend that all prospective investigators/ study personnel have a QAIP Study Initiation Visit. Performing a study correctly from the beginning can prevent a lot of aggravation later. As a research novice, I found this assistance very valuable."

QAIP

QUALITY
ASSESSMENT AND
IMPROVEMENT
PROGRAM

To schedule a **QAIP Study Initiation Visit,**
please contact:
Michelle P. Taylor, QAIP Coordinator
315-464-4328

For more information, go to
www.upstate.edu/researchadmin/compliance/qaip

UPSTATE
MEDICAL UNIVERSITY

Office of Research Administration
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OFFICE OF RESEARCH ADMINISTRATION

QAIP

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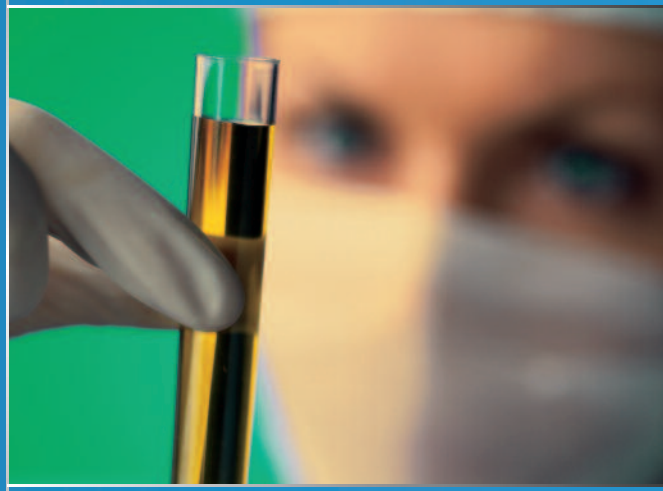

A QAIP Study Initiation Visit is
Preventive Care for Your Study Site

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www.upstate.edu/researchadmin/compliance/qaip

QUALITY ASSESSMENT AND IMPROVEMENT PROGRAM

What is QAIP?

The Quality Assessment & Improvement Program (QAIP) was established in the fall of 2005 to assist investigators in attaining full compliance with governmental and institutional rules and regulations pertaining to human subject research.

The QAIP is a post (IRB) approval monitoring program aimed at providing subjects with an extra level of protection by reviewing the conduct of the study in real time. Routine Reviews are conducted by the QAIP coordinator for IRB-approved research studies; while Directed Reviews are conducted in response to problems with compliance, complaints, or at the request of the IRB. The program also provides initiation visits and continuing assistance and ongoing education to investigators and their staff with regard to human subject research and compliance issues.

QAIP Study Initiation Visits are Available for New Studies That Have Received IRB Approval

The QAIP Coordinator will provide:

- assistance with set-up/organization of study records and required documents;
- instruction concerning local IRB reporting requirements for:
  - I. adverse events
  - II. amendments
  - III. continuing review
  - IV. data safety and monitoring reports
  - V. protocol deviations;
- education about the informed consent process and documentation
- clarification of confidentiality and HIPAA issues.

Schedule a QAIP Study Initiation Visit if You:

- are a new investigator or coordinator
- are an investigator with no study coordinator
- have questions about IRB reporting requirements
- are not assisted/monitored by other entities (e.g. a sponsor)
- would like assistance with study setup before enrollment begins

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A QAIP Study Initiation Visit is:
PRACTICAL, PROACTIVE, PAINLESS

PRACTICAL
Provides straightforward "nuts and bolts" information and a list of specific recommendations.

PROACTIVE
"Preventive care" for your study site, avoiding potential problems before they develop.

PAINLESS
The visit will be conducted based on your needs and within your timeframe.

For questions, or to schedule a QAIP Study Initiation Visit, please contact:

Michelle P. Taylor RPA-C, MS, MT(ASCP)
QAIP Coordinator
315-464-4328
taylormi@upstate.edu

For more information, go to
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