Research Education

News

Upcoming Research
Education
Opportunities

September 18th "Achieving High Quality Clinical Research Seminar Series"

"Non Compliance"

Presented by:
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Executive Director RSRB

Date: Tuesday, September 18, 2012
Time: 12:15 -1:15 pm
Place: School of Nursing - Helen Wood Hall Auditorium, 1W304

What are GOOD CLINICAL PRACTICES (GCPs)?

- GCPs are recognized as the standard operating procedure for conducting clinical trials
- Phrase coined by the pharmaceutical industry
- Combination of Regulations, International Conference on Harmonization (ICH) guidelines, Food & Drug Administration (FDA) Form FDA 1572, Ethical Codes, FDA Guidelines and other Guidance documents
- Not found in one place

Quality Improvement News

Did you know?

NYS and the Department of Health (DOH) require consent for HIV testing and amended the law for HIV testing in 2010. If an HIV test result is part of your study’s eligibility criteria, subjects who opt to undergo the HIV testing for research participation must sign an HIV consent form (in addition to the study consent) and receive the required education about HIV testing prior to having the test. Please refer to this DOH website for additional information.

http://www.health.ny.gov/diseases/aids/testing

You may find the HIV Testing Toolkit helpful:

http://www.health.ny.gov/diseases/aids/testing/docs/testing_toolkit.pdf
RSRB News

Procedures for Home Visits:

- Will consent be obtained prior to home visit? If no, how and where will consent be obtained to ensure privacy and confidentiality?
- How will privacy be protected at the home when conducting the study intervention?
- What steps will be taken to ensure the safety of the researcher traveling to the home and at the home?
- Are there mandated reporters as part of the research team? If yes, how will the researcher report the possible abuse or illegal behaviors which may be observed or reported during the home visit? How will the subject be informed of researchers reporting?
  - Consent form language: “The researchers are required to report information regarding potential child abuse or neglect reported by you or observed at your home during the research visit. The researcher will also report if there is a reasonable suspicion, based on information provided by you or observed during the research visit at your home that you may present a danger of harm to others or that you may harm yourself unless protective measures are taken.”
- Will the study activities be conducted using the same methods (computer versus paper, video recording, blood draws)?
- Will payment be provided in cash and if yes, how will you ensure safety of researcher carry cash/gift card?

Please note that the consent form language and the questions to be asked may be modified somewhat depending upon the study to be conducted at the home visit.