From: OC GCP Questions
To: [redacted]
Subject: Informed Consent process
Date: Monday, May 18, 2015 11:40:24 AM

Good morning –

Yes the clinical investigator (PI) can delegate tasks including the consenting patients (subjects).

See link below to A Guide to Informed Consent. The witness role is also mentioned in this guidance.

Search for FDA Guidance Documents > A Guide to Informed Consent - Information Sheet It states --

The Consent Process

Informed consent is more than just a signature on a form, it is a process of information exchange that may include, in addition to reading and signing the informed consent document, subject recruitment materials, verbal instructions, question/answer sessions and measures of subject understanding. Institutional Review Boards (IRBs), clinical investigators, and research sponsors all share responsibility for ensuring that the informed consent process is adequate. Thus, rather than an endpoint, the consent document should be the basis for a meaningful exchange between the investigator and the subject.

The clinical investigator is responsible for ensuring that informed consent is obtained from each research subject before that subject participates in the research study. FDA does not require the investigator to personally conduct the consent interview. The investigator remains ultimately responsible, even when delegating the task of obtaining informed consent to another individual knowledgeable about the research.

Additionally, FDA recently issued a new draft guidance on informed consent that is still out for public comment. Please see the link below.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf

The consent process should be adequately documented in the study files. If the clinical investigator (PI) or attending physician is consenting the subjects, FDA would not consider this undue coercion. Please see the section #2 in the guidance above that discusses coercion and undue influence.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hh.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]

Sent: Friday, May 15, 2015 11:59 AM
To: OC GCP Questions
Subject: Informed Consent process

To Whom it May Concern,

There has been a policy implemented at my institution that only allows PI's or Attending Physicians to consent the subjects. In my previous experience, the PI was able to delegate the responsibility to appropriate research staff most of which did not have a medical license of any sort. We were audited 3 times by the FDA and the consent process documentation was always sufficient.

A few of my concerns with this policy…

1. Lacking documentation of complete process if only the investigator is allowed to consent to subject
2. If the patient is seen for a 30 min visit and signs consent within that time –every time. Will that look to the FDA as insufficient time allowance to make a decision?
3. With it being only the Physician/attending physician would this be looked at by the FDA as intimidation or coercion?

Is there any data that shows using a research coordinator/research staff to conduct/document the informed consent process vs the PI/attending physician is better or worse as far as FDA findings are concerned?

Any insight from you would be most helpful.

Best regards,
[redacted]