From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, September 04, 2003 11:16 AM
To: [redacted]
Subject: RE: CRA certification

Dear [redacted],

Your questions about certification requirements was sent to me for response.

There are no certification requirements for clinical research associates (CRAs), or for that matter, any party, under FDA's good clinical practice (GCP) regulations. FDA does not conduct or sponsor any formal training or certification programs in GCP nor does FDA itself certify study staff.

There are many professional groups and organizations that do have such training and/or certification programs. We are familiar with programs conducted by the Association for Clinical Research Professionals (ACRP), the Drug Information Association (DIA), and the Pharmaceutical Education and Research Institute (PERI), among others. However, FDA can not endorse any particular training or certification program.

I hope this information is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

Phone: 301/827-3340
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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [redacted]
Sent: Wednesday, September 03, 2003 11:21 AM
To: gcpquestions@oc.fda.gov
Subject: CRA certification

Dear FDA personnel,
I am [redacted] a Clinical
Research Associate (CRA) in a [redacted] or Contract/Clinical Research Organization (CRO). Several job descriptions I have seen on the Internet does not include requiring CRA certification as a

qualification for applying for those positions. I was
told from a staff member of the [redacted] that one must have an
official CRA certification course in order to become a
CRA and that the FDA regulates the certification. Are
these statements factual? Please commment.

Kindly reply electronically or by phone at
[redacted]