

Professional Development

Human Research Certification—Is It for You?

CIP, CIM, CRA, CRC, CPI, CCRP, and CPI—what do these sets of initials have in common? All represent certification for work in the field of research with human subjects.

Certification represents a standard for experience and professional knowledge that supports awareness of and adherence to ethical principles in human subject research. As with a college degree, though, certification is not an endorsement or a guarantee of an individual's qualifications or performance.

Over the past 20 years, research with human subjects has evolved from investigator-led research protocols conducted at single institutions to collaborative protocols conducted at multiple institutions. In that time, human research protections has become a highly respected professional field.

Oversight of research with human subjects also has become far more complex, and recent scrutiny of human research practices has revealed the need for a far greater degree of individual and institutional accountability than in the past. The certification of individuals, along with the accreditation of institutional programs, is a benchmark for standards for protecting human research subjects.

Who benefits from certification? In addition to a sense of professional achievement, certified human subject research professionals enjoy enhanced career opportunities. Many institutions seek to hire certified persons; others support certification as an aspect of professional development. Certified IRB professionals strengthen an institution's human research protection program by improving IRB administration and regulatory compliance. Most important, research subjects benefit from participating in research at institutions staffed by certified professionals who are well-attuned

to subjects' safety and well-being.

Two certification programs have been established for IRB professionals: the Certified IRB Professional (CIP), which is sponsored by the Council for the Certification of IRB Professionals; and the Certified IRB Manager (CIM), sponsored by the National Association of IRB Managers. Both programs have published mission statements and maintain eligibility criteria, a "Body of Knowledge," and testing and recertification requirements.

The CIP test, offered twice annually at over 700 testing sites, challenges candidates' knowledge of four major areas: foundations and concepts of IRB practice, organizational and personnel knowledge, IRB functions and operations, and records and reports. Certification is valid for three years. Currently, some 2 percent of the nearly 900 CIP-certified individuals are either military personnel or Department of Veterans Affairs staff members. For more information see www.ptcny.com.

The CIM test, also offered twice annually, is an "open book" exam offering extra credit questions. Candidates are allowed six weeks to complete the exam, which tests their knowledge on such topics as the responsibilities of a research assistant, legal consent, retrospective chart review, records management, IRB ethics, government compliance, deception, pharmacy administration, and site audit. Certification expires on June 30 three years from the year awarded. About 700 individuals, mostly civilians, hold the CIM credential. See www.naim.org/index.htm for details.

Certification programs aimed at research coordinators, research assistants, and clinical investigators are described below.

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Significant Changes from "C" to "D"

The DON HRPP has compiled a comprehensive table of the key changes in policy that are reflected in the current Navy Human Research Protection Policy, SECNAVINST 3900.39D, which replaces SECNAVINST 3900.39C. The table is accessible on the DON HRPP website at:

<http://navymedicine.med.navy.mil/humanresearch/>

and will be accessible at the Research Protections Division, Office of Naval Research website at:

http://www.onr.navy.mil/sci_tech/34/343/

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The Clinical Research Associate (CRA) monitors the administration and progress of a clinical trial on behalf of a sponsor. Candidates for CRA certification must have a college degree plus relevant work experience. Recertification is required every two years. About 6,100 CRAs have been awarded.

Some 11,700 Clinical Research Coordinators (CRCs) work at clinical research sites under the immediate direction of a principal investigator. To meet eligibility requirements, at a minimum, individuals must have a high school diploma or equivalent, and at least two years experience enrolling subjects, conducting subject study visits, and maintaining source documents. Recertification is required every two years.

One of the newest certification programs is the Clinical Trial Investigator (CTI). A CTI works at clinical research sites as the non-physician investigator whose research is conducted under Good Clinical Practices and Food and Drug Administration regulations. Candidates must be a doctoral level or equivalent clinical research professional, e.g., PhD, PharmD, Doctor of Nursing Science, Nurse Practitioner, or Physician's

Assistant, and have two years' experience. Currently 16 persons are certified as CTIs.

The CRA, CRC, and CTI are sponsored by the Association of Clinical Research Professionals (ACRP). See <http://www.acrpnnet.org/> for more information.

A Clinical Research Professional (CCRP) works as a clinical researcher, research nurse, administrator, coordinator, consultant, or educator in clinical trials research. Membership in the Society of Clinical Research Associates (SoCRA) and a combination of work experience and degree are necessary for a three-year certification. More than 5,100 CCRPs support clinical research. The CCRP is sponsored by SoCRA; see <http://www.socra.org/> for details.

The Certified Physician Investigator (CPI) is a physician (M.D. or equivalent degree) who serves as an investigator, supervises or designs clinical trials, and accepts responsibility for the safe and ethical conduct of clinical trials. In addition to the medical degree or equivalent, experience and a license are required for the two-year certification. The Academy of Pharmaceutical Physicians and Investigators (<http://aapp.org/file.php?ID=Certification+Info>) sponsors the CPI.

Contracted Animal Care

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Affairs: 202-762-0253/0252), your servicing Staff Judge Advocate, or contracting office. The level to which DoD dictates course content, class participants, or even location will affect the answer.

Commercial combat trauma training is a difficult topic. Some medical operators seek classes prior to deployment, and point to the studies and "lessons learned" reports that extol its benefits. A key question is how the classes are provided—buying seats in a class, providing it on a base, etc.

The Vice Chief BUMED recently signed policy (NAVMED Policy 07-007) requiring that all commercial combat trauma training have a veterinary review

regardless of how many DON folks attend, method of funding, or location.

The Joint Technical Working Group (Animal Care) of the Armed Services Biomedical Research Evaluation and Management (ASBREM) is drafting a similar DoD policy that should be complete by late summer as a policy letter to augment the SECNAVINST.

We're obliged to help keep the DoD on the moral high ground regarding animal care and use. Let's work together to do our best.

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