

Get Ready for Compulsory Clinical Investigator Training

Janet F. Zimmerman, MS, RN, Clinical Research Training Consultant, Newtown, PA

ON MAY 23, 2000, DR. DONNA SHALALA, *Secretary of the U.S. Department of Health and Human Services (HHS), unknowingly endorsed T2K — Training 2000 — a new era in training initiatives for the global clinical research community.¹ In her press conference, Secretary Shalala announced several initiatives to further strengthen federal oversight of biomedical research.*

One of these mandates is to aggressively improve how clinical investigators and institutional review board (IRB) members are prepared for their role and responsibilities in protecting human subjects.²

Two HHS agencies, the National Institutes of Health (NIH) and the Food and Drug Administration (FDA), will collaborate on this HHS training directive along with the newly created Office for Human Research Protections (OHRP).^{*} Their goal is “to ensure that all clinical investigators, research administrators, IRB members and IRB staff receive appropriate research bioethics training and human subjects research training.”³

NIH REQUIRES INVESTIGATOR TRAINING

NIH responded quickly to the Secretary’s mandate for better clinical investigator training. On June 5,

* OHRP was formerly called the Office for Protection from Research Risks (OPRR), which was located at NIH. In June 2000, OPRR was elevated to the HHS department level, assigned to the office of the Assistant Secretary for Health (ASH) and renamed the Office for Human Research Protections. The web site is <http://ohrp.osophs.dhhs.gov>.

2000, NIH announced that all investigators who submit an application for a grant or contract, or who receive a new or non-competing award for research involving human subjects must include evidence of education in human subject protection. This education is required for each investigator and all “key personnel”

listed and is effective October 1, 2000.⁴

I predict that NIH’s prerequisite will become the new standard for anyone conducting clinical research, whether they receive federal funds or not. It is likely that FDA will also seek a similar standard to verify clinical investigator qualifications and compliance.

REACTION TO HUMAN TRAGEDY

Secretary Shalala’s new directives were at least in part precipitated by the gene transfer clinical trials conducted at the University of Pennsylvania. In September 1999, an 18-year-old male research subject died and in January 2000, FDA halted the clinical trial. Unfortunately, it again required a human tragedy reported by the press for the clinical research community to implement improvements in current standards for human subject protection.

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As we end a century of too many sad and avoidable events in human research, the global clinical research community finally recognizes that investigator training is a core component of human subject protection; it can no longer be an option. Regrettably, the global clinical research community, in particular, sponsors, institutional review boards/independent ethics committees (IRBs/IECs), and investigators, has not been proactive in raising standards to protect human subjects. Consequently, we are now forced to react.

UNCLEAR GUIDANCE

While this initial HHS directive is commendatory, it raises several questions. HHS gives little specific guidance other than "appropriate research bioethics training and human subjects research training." Questions regarding content, length, format and frequency will be interpreted widely.

Some will view this as another annoying order and opt for the easiest and shortest route to satisfy

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requirements. Others will take this mandate seriously and genuinely strive to improve their standard for human subject protection by implementing effective training programs for clinical investigators and staff.

The global clinical research

community should not view clinical investigator training as something we *have* to do, but rather something we *want* to do. Anything that helps to raise standards to ensure better protection of human subjects is the right way to conduct clinical trials in the 21st century.

¹ JF Zimmerman, "Welcome to T2K!" *The Monitor*, Spring 2000, page 47.

² HHS Press Release, May 23, 2000, "Secretary Shalala Bolsters Protections for Human Research Subjects," available at <http://www.hhs.gov/news/press/2000pres/20000523.html>

³ Ibid.

⁴ NIH Guide Notice, June 5, 2000, "Required Education in the Protection of Human Research Participants" available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>

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Janet F. Zimmerman, MS, RN
President

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