From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, June 06, 2005 9:02 AM
To: [Redacted]
Subject: RE: Institutional Review Board - ICH Guideline (E6)
Dear [Redacted]:

Your question to the GCP Questions e-mail account was forwarded to me for a response. While the two terms are virtually synonymous, there are some differences. The term "institutional review board" (IRB) is defined in US regulations. "Independent ethics committee" (IEC) is a more generic term for any ethical committee that reviews research. The ICH E6 has been adopted as official "guidance" in the US. To fully understand the difference and why the two terms were used, you may find the following explanation of the difference between "regulations" and "guidance" to be helpful.

Sponsors, monitors, clinical investigators, and contract research organizations (CROs) that conduct or assist in the conduct of clinical studies for drugs, biologics, and medical devices *in the United States* must comply with FDA's regulations for the conduct of such studies. Likewise, ***IRBs*** that review and approve these studies must also comply with FDA's regulatory requirements. FDA's regulations are found in Title 21 of the Code of Federal Regulations (21 CFR). I have listed the specific sections that apply to clinical investigations below:

21 CFR 50: Protection of Human Subjects (Informed Consent)
21 CFR 56: Institutional Review Boards
21 CFR 54: Financial Disclosure by Clinical Investigators
21 CFR 312: Investigational New Drug Application
21 CFR 320: Bioavailability and Bioequivalence Requirements
21 CFR 812: Investigational Device Exemptions

Regulations are enforceable under the Federal Food, Drug and Cosmetic Act. As part of FDA's bioresearch monitoring program, FDA sends its own field investigators out to inspect sponsors, monitors, clinical investigators, CROs, and IRBs to ensure that these establishments have followed FDA's regulations during the conduct of the studies. Should FDA's field investigators uncover any deviations from the regulations, then FDA can take enforcement action. Enforcement actions include sending a regulatory letter to the firm, and administrative sanctions (e.g., disqualification of a clinical investigator; requiring an IRB to withhold approval of new studies or directing that no new subjects be added to ongoing studies). FDA may also refer cases for criminal prosecution.

Guidance, on the other hand, represents FDA's current thinking on a topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach can be used if the approach satisfies the requirements of the applicable statutes and regulations. Anyone

who wishes to discuss an alternative approach may contact the FDA staff responsible for implementing the guidance. In contrast to regulations, guidance is ***not*** enforceable.

So why were both terms used and what does this mean with respect to the ICH E6 "Good Clinical Practice: Consolidated Guidance"? FDA has been part of the ICH process since its inception. When the E6 was developed, it was agreed that there might be differences in some national GCP requirements between the U.S., the EU, and Japan. In particular, ethics committee requirements were more detailed in the U.S. than the EU and Japan --- and EU and Japanese representatives did not believe at that time that they were able to adopt all U.S. regulatory requirements for IRBs/IECs as part of ICH.

As I mentioned earlier, the US adopted ICH E6 as guidance. U.S. regulatory requirements (i.e., FDA regulations) ***must*** be met for studies conducted *in the United States.* For studies conducted outside of the U.S. but in ICH regions, compliance with the provisions of ICH E6 ensures that that the studies will be accepted for review by FDA as non-U.S., non-IND studies (under FDA regulations for accepting such non-U.S., non-IND studies). [See 21 CFR 312.120.]

You may access FDA's regulations and guidance documents from the Good Clinical Practice webpage: http://www.fda.gov/oc/gcp

This is probably more than you ever wanted to know about the "difference" between the two terms, but I hope it clears up any confusion you may have had.

Sincerely,

Carolyn Hommel
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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: Monday, June 06, 2005 7:33 AM
To: gcpquestions@oc.fda.gov
Subject: Insitutional Review Board - ICH Guideline (E6)

Dear Sir,

While reviewing the ICH - GCP guideline (E6), we came across two terms IRB and IEC, but we feel both are same. Is there any difference? If not why two different nomenclatures?

Waiting for your valuable reply.

Regards
[Redacted]

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