From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, January 13, 2005 11:28 AM
To: [purged]
Subject: RE: Financial Disclosure and 1572 in Japan

Dear Mr. [purged]:

You asked if a sponsor would need to collect a Form FDA-1572 (1572) from clinical investigators in Japan who are conducting a study of a diagnostic device. The 1572 is used only with studies involving investigational drugs and biologics. For device studies, sponsors are generally required to obtain a "signed investigator agreement" that collects information very similar to that collected on the 1572 [See 21 CFR 812.43].

Some categories of investigations, as described at 21 CFR 812.2(c), are exempt from the requirements in 21 CFR 812, including investigations involving diagnostic devices, which are described in 21 CFR 812.2(c)(3). This section states, "This part [812], with the exception of § 812.119, does not apply to investigations of the following categories of devices:...

"(3) A diagnostic device, if the sponsor complies with applicable requirements in § 809.10(c), "In Vitro Diagnostic Products for Human Use" and if the testing:

"(i) Is nonirrusive,

"(ii) Does not require an invasive sampling procedure that presents significant risk,

"(iii) Does not by design or intention introduce energy into a subject, and

"(iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure."

If the diagnostic device employed in your study meets all of the criteria listed above, then it would be exempt from the requirements of 21 CFR 812, and the sponsor would not be required to collect a "signed investigator agreement".

You also asked if information about the financial interests of the clinical investigators in Japan would need to be provided. I have pasted in several questions and answers from FDA's Guidance on Financial Disclosure by Clinical Investigators that seem applicable:

Q 20: Do applicants need to provide information on investigators who participate in foreign studies?

A: Yes, applicants should include either a certification or disclosure of information for investigators participating in foreign covered studies. Where the applicant is unable to obtain the information despite acting with due diligence, the applicant may submit a statement documenting its efforts to obtain the information. In this case, it is unnecessary to submit a certification or disclosure form.

Q 24: Are clinical investigators of in vitro diagnostics (IVDs) covered under this regulation since they often involve specimens, not human subjects?

A: Yes. Applicants who submit marketing applications for IVDs must include the appropriate financial certification or disclosure information. Under section 21 CFR 812.3(p), "subject" is defined as a "human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control." Thus, an investigation of an IVD is considered a clinical investigation and, if it is used to support a marketing application, it would be subject to this regulation.

Q 12. What does FDA mean by the definition of clinical investigator and subinvestigator? Is it necessary to collect financial information on spouses and dependent children of subinvestigators?

[This is an excerpt from the answer]:

A: The definition of "clinical investigator" in Part 54 is intended to identify the individuals who should be considered investigators for purposes of reporting under the rule, generally, the people taking responsibility for the study at a given study site. For drugs, biological products and devices, it should be noted that hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make direct and significant contribution to the data are not meant to be included under the definition of clinical investigator. For purposes of this financial disclosure regulation, the term investigator also includes the spouse and each dependent child of the investigator and subinvestigator.

For medical devices, clinical investigators are defined as individual(s), under whose immediate direction the subject is treated and the investigational device is administered, including follow-up evaluations and treatments. Where an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. In general, investigators and subinvestigators sign "investigator agreements" in accordance with 21 CFR 812.43(c) and it is these individuals whose interests should be reported. For studies not conducted under an FDA-approved IDE, (that is, a non-significant risk IDE or an exempt study), the sponsor would need to identify the investigators and subinvestigators they considered covered by the rule in form 3454 and 3455. We expect that there will be at least one such person at each site.

The complete financial disclosure guidance can be accessed from FDA's Good Clinical Practice website (http://www.fda.gov/oc/gcp; once there click on "Guidance and Information Sheets") or by pasting the following into your web browser:

http://www.fda.gov/oc/guidance/financialdis.html

I hope this 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
Fax: 301/827-3169

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: [purged]
Sent: Sunday, January 09, 2005 9:08 AM
To: gcpquestions@oc.fda.gov
Subject: Financial Disclosure and 1572 in Japan

To Whom It May Concern

If someone is conducting a diagnostic device study in the US and Japan, do they need to collect a 1572 in Japan and Financial Disclosure from the clinical investigator for the following scenario. The study would only involve collecting one nasal sample by a swab to confirm flu then testing the sample. It is a very simple study to identify a new method of identifying flu in patients.

In Japan they may be reluctant complete a US document such as a 1572. Do you have any suggestions.

Best regards,
[purged]