From: Hommel, Carolyn - OC
Sent: Thursday, July 06, 2006 4:08 PM
To: Montgomery, Carl J
Cc: Fujiwara, Ty; Murphy, Patricia (ORA); Martinez, Joel; Massimilla, L Glenn; Kuchenthal, Linda R; Koller, Ronald; Matson, Sharon L; McClure III, Hugh M; McGirl, Gerald N
Subject: RE: FDA Press Release/FDA Announces New Initiative to Modernize the Regulation of Clinical Trials and Bioresearch Monitoring

Carl,

In answer to your question, we issued and posted revisions to 5 of the information sheets in early 2006. Here's a direct link to the Information Sheets webpage:

http://www.fda.gov/oc/ohrt/irbs/default.htm

You can also get there from the GCP website: http://www.fda.gov/oc/gcp ; once there, click on "Guidances and Information Sheets" in the middle column, and then click on "FDA Information Sheet Guidances...". The ones we just revised have "(2006)" posted after them, so they're pretty easy to pick out. We have about 3 more in clearance even as we speak, so keep checking that page for updates.

As for publishing them in a volume, I haven't heard of any plans to do so--it's just too difficult to keep a bound copy up to date.

Hope this helps,

Carolyn
301-827-9105

-----Original Message-----
From: Fujiwara, Ty
Sent: Wednesday, July 05, 2006 10:34 AM
To: Hommel, Carolyn - OC
Subject: FW: FDA Press Release/FDA Announces New Initiative to Modernize the Regulation of Clinical Trials and Bioresearch Monitoring

Hi Carolyn....
first day back, and away-y-y-y we go....
Can you get back with Carl on his question.

Thanks a bunch!
ty

From: Montgomery, Carl J
Sent: Wednesday, June 28, 2006 8:33 AM
To: Fujiwara, Ty
Subject: FW: FDA Press Release/FDA Announces New Initiative to Modernize the Regulation of Clinical Trials and Bioresearch Monitoring

Hi,

Have you guys heard anything about these new information sheets? If you have, please let me know how to get some. I am asked all the time when the updates are coming.

Thanks,

Carl

-----Original Message-----
From: Montgomery, Carl J
Sent: Wednesday, June 28, 2006 7:01 AM
To: Matson, Sharon L
Subject: FW: FDA Press Release/FDA Announces New Initiative to Modernize the Regulation of Clinical Trials and Bioresearch Monitoring

Hi,

This was a very interesting article but what really caught my eye was the section on the new information sheets which were published in 1/2006. Have you seen them?

When the 1998 update came out, I found out about them when an IRB showed me their copy and commented how nice the new bound edition was. It was one of my better firms & folks I have known for years so I was very blunt & told them I had no idea they were out. They were stunned since they knew that I was the BIMO Monitor for KC.

I just left Gerry a message on his cell phone asking him if he knew how we could get copies.

Bye,

Carl

-----Original Message-----
From: McGirl, Gerald N
Sent: Wednesday, June 28, 2006 6:25 AM
To: Matson, Sharon L
Cc: Montgomery, Carl J; Murphy, Patricia (ORA); Martinez, Joel; Massimilla, L Glenn; Kuchenthal, Linda R; Koller, Ronald; McClure III, Hugh M
Subject: RE: FDA Press Release/FDA Announces New Initiative to Modernize the Regulation of Clinical Trials and Bioresearch Monitoring

Hi Sharon,

I am currently in Rockville at the Advanced BIMO course. I will pass information along if anything comes up. I will be in the San Francisco office next week -- perhaps we can talk after Independence Day.

Have a superb holiday week-end!

Warm regards,

Gerry

From: Matson, Sharon L
Sent: Tuesday, June 27, 2006 11:26 AM
To: McGirl, Gerald N
Cc: Montgomery, Carl J; Murphy, Patricia (ORA); Martinez, Joel; Massimilla, L Glenn; Kuchenthal, Linda R; Koller, Ronald; McClure III, Hugh M
Subject: FW: FDA Press Release/FDA Announces New Initiative to Modernize the Regulation of Clinical Trials and Bioresearch Monitoring

Hi Gerry,

Can you keep us posted with any news or insight you gain on what this means for field BIMO as it evolves, including: "***taking appropriate opportunities to leverage existing oversight done by private entities to accomplish the Agency's risk minimization goals." ?? All info appreciated!

Best regards,
Sharon

From: Seefeld, Susan
Sent: Tuesday, June 27, 2006 9:20 AM
To: ORA CER MIN All Employees
Subject: FW: FDA Press Release/FDA Announces New Initiative to Modernize the Regulation of Clinical Trials and Bioresearch Monitoring

FOR IMMEDIATE RELEASE **Media Inquiries: Laura Alvey**
P06-86 **301-827-6242**
June 26, 2006 **Consumer Inquiries: 888-INFO-FDA**

FDA Announces New Initiative to Modernize the Regulation of Clinical Trials and Bioresearch Monitoring

The Food and Drug Administration (FDA) today announced a series of new policy and regulatory developments to strengthen the Agency's oversight and protection of patients in clinical trials and the integrity of resulting data in an effort to modernize the agency's approach to bioresearch monitoring as part of the Critical Path Initiative. The Human Subject Protection and Bioresearch Monitoring (HSP/BIMO) Initiative will facilitate the modernization of the regulation of clinical trials and bioresearch monitoring, specifically the protection of human subjects and the integrity of data in clinical trials, and encompasses devices, foods, human drugs, biological drug products and veterinary medicine.

The new effort is part of an HHS-wide initiative to employ recent advances in basic science, including genomics and molecular analysis, in order to bring about more effective development and review of therapies, and to enable increasingly targeted and individualized care management for patients.

"As clinical trials continue to evolve, in particular becoming increasingly large, decentralized and global, the FDA's approach to bioresearch monitoring and human subject protection must also evolve and modernize," said Janet Woodcock, FDA Deputy Commissioner for Operations at this year's Drug Information Association annual meeting. "BIMO will help FDA modernize biomedical research monitoring making the most efficient use of its resources to help ensure the safe conduct of clinical trials, including taking appropriate opportunities to leverage existing oversight done by private entities to accomplish the Agency's risk minimization goals."

Clinical trials have evolved dramatically since FDA first began inspecting them in 1977. In an effort to protect the rights and welfare of human subjects and to verify the quality and integrity of data submitted for review, FDA established over time a bioresearch monitoring program that included the development and implementation of compliance programs to provide guidance for inspections of investigators, sponsors, contract research organizations, institutional review boards and bioequivalence facilities. With the expansion of clinical trial studies and sites, electronic record-keeping in the studies, and greater participation by vulnerable subjects in clinical trials, the role of FDA's bioresearch monitoring compliance programs must expand and evolve as well. The HSP/BIMO Initiative addresses that need.

Over the past year and a half, FDA has carefully inventoried its programs and identified issues to launch the HSP/BIMO Initiative. As this initiative moves forward, FDA will continue to gather additional issues for the initiative and related information from internal and external stakeholders, e.g., industry, academic, and government activities and programs, and intends to conduct workshops and create other opportunities for public input.

Janet Woodcock, M.D., Deputy Commissioner for Operations, will chair the HSP/BIMO steering committee which is comprised of representatives from the Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), Center for Food, Safety, and Nutrition (CFSAN), Center for Veterinary Medicine (CVM), Office of Regulatory Affairs (ORA), and the Office of the Commissioner (OC).

Highlights of what has been completed to date include:

- Draft Guidance; Process for Handling Referrals to FDA Under 21 CFR 50.54; Additional Safeguards for Children in Clinical Investigations, published May 2006
- Guidance for Industry – *U*sing a Centralized IRB Process in Multicenter Clinical Trials, published in March 2006
- Guidance for Clinical Trial Sponsors: *E*stablishment and Operation of Clinical Trial Data Monitoring Committees, published in l March 2006
- Information Sheet Guidances for IRBs, Clinical Investigators, and Sponsors, five published in final January 2006

Projects in progress:

- Modernizing adverse event reporting to institutional review boards (IRBs) to accommodate major trend toward multicenter trials (March 2005, held Part 15 Hearing – Adverse Event Reporting to IRBs, currently working on draft guidance)
- Published proposed rule: *Institutional Review Board – Registration Requirements*, FDA reviewing comments
- Finalizing rule: Foreign Clinical Studies not Conducted Under an IND (21 CFR 312.120)

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<< OLE Object: Picture (Metafile) >>