

# Comprehensive Clinical Trials, LLC

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December 4, 2006

Division of Dockets Management

HFA-305

Food and Drug Administration

5630 Fishers Lane

Room 1061

Rockville, MD 20857

RE: Human Subject Protection and Bioresearch Monitoring Initiative

Dear Members of the FDA:

I have worked as a regulatory coordinator for the past four-and-a-half years. I do not hold a degree, but I have worked in the medical field since 1971 in various capacities. I have no formal training in Regulatory Affairs. I learned what I know from a terrific mentor who was my supervisor for four years, and I also learned from various websites including RAPS (to which I belong), your FDA website, and many others that enlightened and educated me.

Now I understand that you are creating the Human Subject Protection and Bioresearch Monitoring Initiative. I do have a comment regarding electronic issues, specifically when an outside company manages a website for the retrieving of and sending in regulatory documents for medical research studies.

I believe that more training needs to be done for companies, especially if they are not experienced in the medical field, who manage these types of websites. Specifically, I have had the experience of working with a website called Intralinks, from which I retrieved regulatory documents to be completed and then faxed the documents with a special fax cover back to Intralinks, where they are posted on a particular study's "hub" and are available to the Sponsor and the IRB. There is a lot of redundancy in my opinion, as after faxing them and getting the "OK" from the sponsor, I still have to send in the original documents to the sponsor. However, I do understand the premise behind using a website such as this in that the sponsor can easily review and give me feedback as to the correctness of the documents or any changes that need to be made.

Too often, I find that when I log in to Intralinks and need to go to a study that we are taking part in, I see other Principal Investigator's names listed on our site's "hub" with their particular documents posted for me and all the world to see. Several times, I have had to bring this to the attention of the Intralinks contact as well as the study sponsor, and then these unknown Principal Investigators are removed from our site's space. More training needs to be done, and perhaps some type of programming put in place so that only my particular Principal Investigator's information can go on my log-in for a particular study. This way, it would prevent other eyes from seeing who is also participating and what their documents look like.

(Continued)

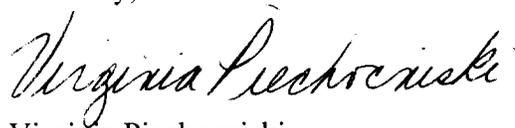
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have also had the experience of using a website that is managed directly by the sponsor (Novartis is one that comes to mind). Now, this presents a different type of issue. I have found that even though the Sponsor has a "portal" or a website where documents can be retrieved, this sometimes causes the issue of our site receiving several copies of the same document (IND reports are an example). With some sponsors, I receive a fax of a document or report, then I receive a hard copy in the mail, and then I receive an email directing me to the portal or website where the same document is waiting for me to retrieve it. So, now I have three copies of the same thing, and most of the time they arrive on different days, so I have the Principal Investigator sign and date all of them ultimately, and this sometimes causes great confusion.

I look forward to reading about the results of the upcoming meeting on December 18<sup>th</sup>, 2006. Thank you for taking the time to read my letter.

Sincerely,

A handwritten signature in cursive script that reads "Virginia Piechocniski".

Virginia Piechocniski  
Regulatory Coordinator  
Comprehensive Clinical Trials, LLC  
West Palm Beach, FL