

Underestimating Regulatory Sophistication in Other Countries

By Norman M. Goldfarb

Given the regulatory compliance problems we have in the United States, it is easy to assume that other countries, especially those in the developing world, have even more problems. However, without good evidence, we should not underestimate the competence of any clinical professional anywhere in the world. The following letter, received from an anonymous source, supports this point.

April 1, 2012

Mr. Alby N. Forsier
Director, Office of Regulatory Compliance
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Mr. Forsier:

The GSOT IRB has been operating in Austin, Texas, for over 20 years. We are proud of our part in making Texas the leading state in the Union for ethical clinical research.

I am writing today to call your attention to a recent spate of problems we have had with study documents from Northern pharmaceutical companies. We live in a richly varied global community and appreciate efforts to communicate effectively, but that is no excuse for any Yankee trying to "pull the wool over our eyes."

The patient letter template below is typical of the documents we are seeing more and more frequently. In the Great State of Texas, you can rest assured that we would never approve this letter on ethical grounds, although it is, in fact, exactly how we always talk among ourselves.

Dear [Patient Name],

Are you feelin' frustrated as a one-legged man at a butt-kicking contest? Nervous as a long-tailed cat in a room full of rockin' chairs? Wore out like a horse been rode hard and put up wet?

Well, we're fixin' to get ready to start testin' an experimental potion that might have you walkin' in tall cotton 'fore the river rises. You can put your boots in the oven and that don't make 'em biscuits, but if you've done it, it ain't braggin'. We've tried the tonic on the neighbor's kids and they's grinnin' like a mule eatin' briars.

This rodeo is big as all hell and half of Texas, but the clowns are getting tuckered, so give us a holler 'fore supper and your future just might be lookin' purtier than two acres of red hogs. We could give it a longer chaw but don't worry 'bout the mule for now, just load the wagon. It's time to paint your butt white and run with the antelope.

Your doctor lady,

[Physician Name], MD

Please consider issuing a guidance document on this matter.

Sincerely yours,

A handwritten signature in black ink that reads "William Nelson". The signature is fluid and cursive, with the first name "William" and last name "Nelson" clearly distinguishable.

William Nelson
Chairman, GSOT IRB
1 Texan Way
Austin, TX 78701

Author

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