

## WIPUS 0.2-201909

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U.S. Department of Health & Human Services  
Centers for Disease Control and Prevention  
National Center for Immunization and Control

Division of Field Epidemiology

1600 Clifton Road, NE Atlanta, Georgia 30333

Telephone: 404-616-1300  
Fax: 404-616-1300  
Email: [field@cdc.gov](mailto:field@cdc.gov)

Website: [www.cdc.gov/field](http://www.cdc.gov/field)

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Clinical trials.  
longstanding

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the agency's thinking to sponsors of clinical trials in the business community and the academic research community about their obligations under FDAAA. The bill, when finalized, will

ing on Chicago, Ill., gov. These factors illustrate the complexity of accurately measuring compliance.

Law with the in Committee

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agency's thinking to sponsors of clinical trials in the [redacted] and the academic

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under FDAAA

Q. Does NIH have sufficient resources and authority to implement the reporting requirements?

NIH has sufficient resources and authority to implement the reporting requirements.



3) Does NIH believe additional



Dear \_\_\_\_\_:

\_\_\_\_\_

identical letter is being sent to \_\_\_\_\_

Enron

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Enron

the agency's thinking, exposure of clinical trials in the business community and the academic research community about their obligations under FD-379. The FD-379, when finalized, will increase our understanding of what the agency expects.

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Dear [REDACTED],

[REDACTED] are necessary to address the issues of underreporting of clinical trials, data and non-compliance with reporting requirements in the [REDACTED] Sector.

I would again like to thank you for your interest in the [REDACTED] compliance.

Sincerely yours,

[REDACTED]

[REDACTED]