BIOTECHNOLOGY INDUSTRY ORGANIZATION

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March 1, 2010

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: FDA–2009–N–0592 RIN No. 0910–AG32: Informed Consent Elements

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the proposed rule on *Informed Consent Elements*.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

GENERAL COMMENTS

We are concerned the language listed below, which FDA suggests be added verbatim, is more technical and sophisticated than most consent forms typically include. Industry typically aims for a sixth to eighth grade reading level in informed consent forms. The language below reads at an advanced level.

"Information, that does not include personally identifiable information, concerning this clinical trial has been or will be submitted, at the appropriate and required time, to the government operated clinical trial registry data bank, which contains registration, results, and other information about registered clinical trials. This data bank can be accessed by you and the general public at www.ClinicalTrials.gov. Federal law requires clinical trial information for certain clinical trials to be submitted to the data bank."

In addition, mandating a specific language (exact wording) is inconsistent with other elements of informed consent as detailed in 21 CFR 50.25, which says what must be addressed but not how to address it. We recommend the informed consent elements should be consistent with other required elements of informed consent and state what must be covered in consent forms but not mandate specific wording.

If specific language is mandated, BIO proposes the alternative language for applicable trials per 402(j)(A)(i) of the PHS Act (42 U.S.C. 282 (j)(1)(A)(i))], "A description of this clinical trial is available on the Internet at www.ClinicalTrials.gov. Once the study is completed, a summary of the results of this clinical trial may also be available on the Internet at www.ClinicalTrials.gov. No information will be included that could identify you or any other participant."

We note that because the rule will apply to global clinical studies, different wording should be used in ex-US consent forms, where (a) "Federal law" and "government operated" aren't clear and (b) data privacy concerns must be addressed. The proposed language is US-centric and may not be applicable in other countries.

Furthermore, the proposed rule does not delineate when informed consent documents would be required to contain the new language or the time point when the Final Rule would go into effect. In order for organizations to comply with the new rule, including adding the language to protocols and implementing them in trials, we recommend a six month grace period after the Final Rule goes into effect for implementation.

We also recommend that guidance be provided by FDA to avert confusion for sponsoring companies and to help ensure consistency from one protocol to another, particularly because investigative sites often conduct multiple studies from various sponsors. Additionally, given that some protocols may be under ethics committee review before the Rule is final, guidance will avoid confusion for ethics committees. We suggest that guidance include the following points:

- For clinical studies that have received at least one favorable ethics committee opinion but patient recruitment has not begun before the Final Rule date, the informed consent template will not be required to contain the language.
- For clinical studies that have received at least one favorable ethics committee opinion and patient recruitment has began before the Final Rule date, the informed consent template will not be required to contain the language and will not be required to be amended to incorporate the new required language. This is because any change to the informed consent at this point means full resubmission to the EC, resulting in major time delays in providing patients access to clinical trials.
- For clinical studies which have been submitted to at least one ethics committee and all IRB/EC rulings are pending, or for clinical studies that have not been submitted to any ethic review committee before the final rule takes effect, the informed consent templates are required to incorporate the new required language.
- For any protocol amendment dated within 30 days of the Final Rule the informed consent must be revised to incorporate the new required language if the amendment requires re-consent.

Conclusion

Thank you for this opportunity to comment on the proposed rule on *Informed Consent Elements*. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/s/

Sara Radcliffe
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