January 21, 2020

Division of Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852


Dear Sir or Madam:

The Advanced Medical Technology Association (“AdvaMed”) is pleased to provide comments on the Food and Drug Administration’s (FDA’s or “Agency”) draft guidance entitled “Certificates of Confidentiality: Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff.”

The Advanced Medical Technology Association (AdvaMed) is the world’s largest trade association representing medical device and diagnostics manufacturers. AdvaMed’s member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

AdvaMed has general and specific comments below.

General Comments
AdvaMed strongly supports the intent of the 21st Century Cures Act and the objective of this draft guidance to: 1) ensure the privacy of human subject research participants’ identifiable, sensitive information and to protect researchers from being compelled to disclose information created or compiled for human research purposes; and 2) to facilitate the issuance of Certificates of Confidentiality (CoCs) for non-federally funded research subject to FDA jurisdiction to sponsors and sponsor-investigators by streamlining the process and reducing the time required to comply with the requirements for CoCs.
AdvaMed has the following recommendations to improve the clarity and understanding of FDA’s CoC process.

Clarity around the term “sensitive information”: FDA should provide more clarity around what is considered sensitive information by providing a definition and providing examples of sensitive information. For example, the National Institutes of Health (NIH) states: “Certificates of Confidentiality may be granted for studies collecting information that if disclosed could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation [emphasis added].” It would also be helpful to include language similar to NIH’s CoC language in the FDA guidance: “By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants.” Providing additional examples to the language on page three defining “identifiable, sensitive information” would also be helpful such as: information about participants’ sexual attitudes, preferences or practices, information about controlled substance abuse or other illegal risk behaviors.

Obligation to report to human subjects on confidentiality of information: In addition to requiring informed consent for the use of identifiable, sensitive information collected in the study, we recommend the guidance include a section that advises sponsors and sponsor investigators to consider communicating with the human subjects when they have obtained a certificate of confidentiality and the protections and any limitations afforded by the CoC. This could also include a description of the types of information the study will collect that are considered sensitive or which could potentially harm participants in the event of a confidentiality breach.

Relationship between CoCs and Changes to Protocols: Because protocols and studies can change, we recommend the guidance address if or when updates or amendments to the CoC may be needed. For example, does the CoC need to be updated if there is a change in the primary investigator or a change in the research goals? Does a CoC ever expire and require a re-application?

Clarification Around Reasons for FDA Refusal of Discretionary CoCs: We recommend that FDA include reasons discretionary CoCs might be rejected, including some examples. Although the guidance does list questions to consider prior to submitting the request under Section IV, it would be helpful to further understand the possible basis for FDA refusal to grant discretionary CoCs.

Template Submission Form: We recommend that FDA add a template CoC submission form as an appendix to the guidance.

FDA Timeline for Issuance of CoC: To ensure that the CoC process minimizes the burden to researchers, streamlines the process and reduces the time to comply with CoC
requirements per the 21st Century Cures Act, we recommend that FDA include in the final guidance, a timeline under which FDA will issue a discretionary CoC to a sponsor or sponsor-investigator (i.e., no more than 60 days).

**Specific Comments**

AdvaMed’s specific comments are attached in table format below.

In closing, thank you for this opportunity to provide comments on FDA’s draft guidance on certificates of confidentiality. Please don’t hesitate to contact me if you have any questions.

Sincerely,

/s/

Tara Federici
Vice President
Technology and Regulatory Affairs
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<td><strong>p.3, Section III, Paragraph 1 line two</strong> To help ensure that discretionary CoCs are issued to those entities who can comply with the requirements of the statutory provision, we <strong>strongly recommend</strong> that only sponsors or sponsor-investigators submit requests for discretionary CoCs (as defined in 21 CFR §50.3, §312.3, §812.3) (i.e., the individual who takes responsibility for or initiates the clinical investigation). This will help eliminate duplicative requests to FDA for the same human subject research. It is our understanding that, typically, sponsors and sponsor-investigators are the entities or individuals who have responsibility and control over information collected and used in research.</td>
<td>We agree with FDA that only sponsors or sponsor-investigators should submit requests for discretionary CoCs. This would avoid the situation where the sponsor could potentially be unaware of the issuance of a CoC. We recommend that FDA strengthen this language and also consider adding language (e.g., in a section about refusal of discretionary CoCs) by clarifying the steps involved in the event someone other than a sponsor submits a request for a CoC, for example, one site in a multi-center trial. In this instance, the sponsor could be unaware that the site requested the CoC and yet have obligations.</td>
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<td><strong>p.3, Section III, Paragraph 2</strong> In considering whether the individual information being collected is “identifiable, sensitive information,” sponsors, sponsor-investigators, and other researchers should be aware of the evolving perspectives as to the identifiability of the information collected. Given current technological capabilities, there is some support for the position that the identity of an individual participating in certain types of research is relatively easy to determine even with limited de-identified data. Genomic data also are often considered <strong>by some</strong> to fall automatically into the category of identifiable, sensitive information; however, this position is not universal.</td>
<td>Genomic data should not automatically be considered to fall into the category of identifiable, sensitive information. There is no clear consensus on this topic. To avoid confusion, we recommend de-emphasis of this example as suggested.</td>
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<td><strong>p. 1, Section I Paragraph 2</strong> For non-federally funded research, <strong>issuance of a request for a CoC is not required but if requested</strong>, may be issued at the discretion of FDA (referred to in this guidance as discretionary CoCs).</td>
<td>We assume FDA does not want the Sponsor to apply for a discretionary CoC for every study if they are able to answer “Yes” to the list of questions. We recommend adding clarifying language that a request to FDA for the issuance of a discretionary CoC be made by those entities and individuals that can answer</td>
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<td>p. 5, Section IV first full Paragraph</td>
<td>We recommend that a request to FDA for the issuance of a discretionary CoC can be made by those entities and individuals that can answer “yes” to all of these questions. A request for a discretionary CoC also should not be made if the human subject research is federally funded. We also prefer that all requests for discretionary CoCs be submitted electronically as described in this section and with the information and assurances as detailed in this section.</td>
<td>“yes” to all of these questions and that desire a CoC. We don't think it is appropriate – nor do we think it is FDA’s intention – to burden every study with a CoC submission. If FDA received a request for every study, such a requirement could significantly delay the start of trials.</td>
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