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January 24, 2020

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

RE: FDA-2019-D-3592 Certificates of Confidentiality; Draft Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff: Availability

Dear Sir or Madam:

I write on behalf of the University of California system in regards to the Food and Drug Administration's (FDA) draft guidance entitled "Certificates of Confidentiality: Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff."

The UC system is comprised of ten research-intensive campuses, six medical schools, and three affiliated U.S. Department of Energy national laboratories. As a system, UC receives approximately $6 billion annually of extramural awards to support research conducted throughout all UC locations, with nearly half of all research funding supported by federal funds.[1]

UC strongly supports the intent of the 21st Century Cures Act and the objective of this draft guidance to: 1) ensure the privacy of human subject research participants; 2) protect researchers from being compelled to disclose information created or compiled for human research purposes; and 3) to facilitate the issuance of Certificates of Confidentiality (CoCs) to sponsors and sponsor-investigators for non-federally funded research subject to FDA jurisdiction by streamlining the process and reducing the time required to comply with the requirements for CoCs.

UC notes the FDA estimate of only 150 annual submissions. This suggests the need for additional information in several key areas. UC offers the following recommendations to improve the clarity and understanding of FDA's CoC guidance.

[1] University of California Accountability Report 2019: https://accountability.universityofcalifornia.edu/2019/chapters/chapter-9.html#9.1.4

Clarity around Identifiable, Sensitive Information

Certificates of Confidentiality are a federal legal tool designed to protect sensitive, identifiable research data from compelled disclosure. Congress first authorized their use in 1970 to facilitate research on illegal drug use. The scope of their use was later expanded to cover mental health research and then again to apply broadly to identifiable, sensitive research data, regardless of topic. While CoCs were initially granted based on the sensitivity of a research study, CoCs are now tied to the identifiability of a participant. This means that the evaluation of certain research projects as "sensitive" will no longer serve to narrow the scope of applicability for when a CoC is required, and there will be inconsistent applications across different recipient institutions.

UC recommends that FDA 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." 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, or information about controlled substance abuse, or other illegal/risky behaviors.

Further guidance about thresholds would also be helpful. For example, many studies collect information about illicit drug use, or even a drug test, as part of eligibility screening. This raises the question of whether FDA considers this sufficient justification for a CoC or if some other higher bar must be met, such as if the collection of comprehensive drug use information at multiple timepoints or if the study is geared specifically toward a population of drug users.

The FDA estimate of only 150 annual submissions suggests a narrow view of when a CoC is justified. **UC recommends that the guidance confirm whether FDA holds a narrow view of what is identifiable and sensitive and provide illuminating examples.**

Discretionary CoCs and IRB Review

The FDA points out that only those entities that can comply with the requirements of the CoC should apply for them. Per the guidance, the FDA indicates that this would be either sponsors or sponsor-investigators. However, as the FDA does not currently require single IRB review for non-federally funded studies that are FDA regulated, such sponsored research may be submitted to dozens of IRBs who will all make their own determinations about the sensitivity and identifiability of the data. Given that each IRB may consider only its own local context, the sponsor may not agree that the data is sufficiently sensitive nor identifiable to warrant a CoC even if a particular IRB determines otherwise. Additionally, it is often the case that directly identifiable data (e.g. subject names, physical addresses, email addresses, social security numbers, etc.) is retained by the investigator and not the sponsor.

As such, we ask that FDA provide guidance on instances when the sponsor is unwilling to file for a CoC and the IRB feels one is required. If the IRB determines that only direct identifiers but not indirect identifiers should be protected, will their documentation to such determination allow a single investigator to obtain a CoC from the FDA? In the case of either scenario, when the sponsor refuses to obtain a CoC for the study would it be more appropriate for the individual investigator to instead seek a CoC from another federal agency (e.g. the NIH)? **UC urges the FDA to allow investigators to be able to apply for a CoC on their own (with the exception of sponsor-investigators), or at least to provide guidance for limited situations in which the local context of a particular site might justify a CoC.**

Consent Language

The NIH provides examples of CoC language to include in consent forms. For example, NIH provides the following sample consent language:

> "To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.
>
> *Exceptions*: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing certain information about you for legal or ethical reasons. For example, we will report information about child abuse, elder abuse, or intent to hurt yourself or others. If an insurer, employer, or other person obtains your written consent to receive research information, we cannot use the Certificate to withhold that information. In addition, the Certificate may not be used to withhold information from the federal government needed for auditing or evaluating federally funded projects or information needed by the FDA, e.g., for quality assurance or data analysis."

We ask for clarification on whether the FDA has suggested informed consent language regarding the CoC, or whether the above language would be acceptable provided that the information about the granting agency is correctly modified.

Clarification around Reasons for FDA Refusal of Discretionary CoCs

We recommend that FDA include reasons discretionary CoCs may be rejected, including some examples. Although the guidance does list questions to consider prior to submitting a request under Section IV, it would be helpful to further understand the possible basis for FDA refusal to grant discretionary CoCs. In addition, should FDA refuse to grant a discretionary CoC, we ask that FDA provide clarifications on what options are available to investigators moving forward, such as applying to another HHS agency.

We appreciate the opportunity to comment on FDA's draft guidance and would be happy to further engage with the FDA in finding workable solutions.

Sincerely,

Lourdes G. DeMattos
Associate Director
Research Policy Analysis & Coordination