**21st Century Cures Act**

1. **Relevant Sections**

**SEC. 2012. PRIVACY PROTECTION FOR HUMAN RESEARCH**

States: ‘‘*(d)(1)(A) If a person is engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs), the Secretary, in coordination with other agencies, as applicable— (i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research if the research is funded wholly or in part by the Federal Government; and*…”

The Act further states:

‘‘*(4) For purposes of this subsection, the term ‘identifiable, sensitive information’ means information that is about an individual and that is gathered or used during the course of research described in paragraph (1)(A) and— (A) through which an individual is identified; or (B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.’*’

<https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf>

1. **NIH Implementation**

NIH issued “Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality (Notice Number: NOT-OD-17-109), Effective Date: October 1, 2017

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>

NIH website on Certificates of Confidentiality (CoC) [<https://humansubjects.nih.gov/coc/index>] provides additional information on the topic.

Purpose: Effective October 1, 2017, NIH has updated its policy for issuing Certificates of Confidentiality (Certificates) for NIH-funded and conducted research, as a result of the need to implement Section 2012 of the 21st Century Cures Act, P.L. 114-255, which states that the Secretary, HHS shall issue Certificates of Confidentiality to persons engaged in biomedical, behavioral, clinical or other research, *in which identifiable, sensitive information is collected*. These Certificates protect the privacy of subjects by limiting the disclosure of identifiable, sensitive information.

* 1. *NIH provides the following guidance:*

To determine if this Policy applies to research conducted or supported by NIH, investigators will need to ask, and answer the following question:

* + 1. Is the activity biomedical, behavioral, clinical, or other research?

If the answer to this question is no, then the activity is not issued a Certificate. If the answer is yes, then investigators will need to answer the following questions:

* + 1. Does the research involve Human Subjects as defined by 45 CFR Part 46?
    2. Are you collecting or using biospecimens that are identifiable to an individual as part of the research?
    3. If collecting or using biospecimens as part of the research, is there a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual?
    4. Does the research involve the generation of individual level, human genomic data?

If the answer to any one of these questions is yes, then this Policy will apply to the research.