NIH Policy for Issuing Certificates of Confidentiality
Effective October 1, 2017

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Director, IRB Administration

NIH Revised Policy

In a nutshell, this policy applies to all biomedical, behavioral, clinical, or other research funded by NIH and commenced or ongoing after December 13, 2016 where the following may occur:

• An individual is identified; or
• There is at least a very small risk that some combination of the information requested or created and other available data could be used to deduce the identity of the individual
NIH Revised Policy

NIH now considers research collecting or using identifiable sensitive information to include:

- All HSR, except exempt research where the data obtained is recorded in a manner that subjects cannot be identified or the identity of the subjects cannot readily be ascertained;
- Research collection or use of biospecimens that are identifiable or for which there is at least a very small risk that some combination could be used identify an individual;
- Research involving the generation of individual level, human genomic data from biospecimens, or use of such data; or
- All research that involves information about an individual for which there is at least a very small risk that some combination of the information could be used identify an individual.

Recipient of Certificate of Confidentiality shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.
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Recipient of Certificate of Confidentiality may disclose information only when disclosure is:

- Required by federal, State, or local laws (e.g., reporting to FDA, communicable disease reporting) excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

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Recipients conducting NIH supported research applicable to this Policy are required

- To establish & maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance the terms and conditions of award.
- To ensure that investigators or institutions not funded by NIH who receives a copy of identifiable, sensitive information protected by a COC under this policy, understand they are also subject to these requirements.
- To ensure that any sub-recipient accessing a copy of identifiable, sensitive information protected by a COC issued by this Policy understand they are also subject to these requirements.
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Informed Consent

For studies in which informed consent is sought, NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you: however the Certificate cannot be used:

1. To resist a demand for information from personnel of the US federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects.
2. To prevent submission of reports that must be disclosed to the federal Food and Drug Administration (FDA) to meet the reporting requirements of the FDA.

If an insurer, medical care provider, or other person obtains your written consent to receive information, then the researchers will not use the Certificate to withhold that information. You should also understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about you or your involvement in this research.
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Next steps:
1. Identify NIH funded studies that are included in this revised policy;
2. Train staff, sub-awardies and all other stake-holders on the non-disclosure requirements.
3. Add language to the consent document and submit a modification to the IRB.

That's all folks!
Are there any questions?