Human Subjects Protection Update
Special Communication
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On September 7, 2017 NIH published a new policy regarding Certificates of Confidentiality (CoC) that went into effect on October 1, 2017. This new policy introduced a number of major changes. We are providing a Question and Answer document to help you implement this new policy as it applies to NIH funded research at Boston Children's Hospital. We urge you to also visit the NIH website and review their questions and answers as they pertain to your investigator responsibilities under this new policy.
Link to website: https://humansubjects.nih.gov/coc/faqs

What is a Certificate of Confidentiality?

A Certificate of Confidentiality (CoC) protects the privacy of research participants enrolled in biomedical, behavioral, clinical or other research. With limited exceptions, researchers may not disclose sensitive information. The CoC prohibits disclosure in response to legal demands, such as a subpoena.

What are the major changes included in this policy?

Prior to October 1, 2017 investigators needed to apply to NIH to request a certificate of confidentiality. This option was mainly used by investigators who collected information about sensitive behavioral research and more recently by some investigators performing genetic research. Effective October 1, 2017 certificates of confidentiality will be automatically issued to NIH-funded grants, cooperative agreements, contracts and intramural research projects funded wholly or in part by the NIH that collect or use identifiable, sensitive information. NIH considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research including exempt research if the recorded information is directly or indirectly linked to identifiers;
- Research involving the collection or use of biospecimens or information for which there is at least a very small risk that some combination of the biospecimen/information, a request for the biospecimen/information, and other available data sources could be used to deduce the identity of an individual;
- Research that involves the generation of human genomic data regardless of the identifiability of the biospecimen. (Note this may include research activities which have been designated "not human subject research" and not require IRB oversight,)

The new policy retroactively applies to research commenced or ongoing on or after December 13, 2016. This policy applies only to NIH. Other federal agencies, the FDA and CDC are expected to develop their own policies.

Will investigators of NIH grants still have to apply to the NIH for a CoC?

No, NIH-funded researchers will no longer have to request a CoC, nor will they receive an actual certificate. NIH will automatically provide a CoC as a standard term and condition in the Notice of Award (NOA) for new and non-competing awards when research falls within

the scope of this policy. The institution is responsible for determining which grants meet the definition as required by NIH. It is important for investigators to know if their grant applies as there are limitations and prohibitions about the disclosure of research data after collection.

Does the CoC still protect the investigator from being forced to disclose research information for legal proceedings?
Currently a CoC protects an investigator from being forced to disclose research information pursuant to Federal, state or local civil, criminal, or legislative proceedings.

What are the investigator's responsibilities under a Certificate of Confidentiality?
Investigators are not permitted to:

- Disclose or provide covered information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding; or
- Disclose or provide covered information to any other person not connected with the research. Investigators are prohibited from making any such disclosures of research information.

Investigators may ONLY disclose identifiable, sensitive information in the following circumstances:

- If required by other Federal, State, or local laws, such as for reporting of communicable diseases
- If the subject consents; or
- For the purposes of scientific research that is compliant with human subjects regulations

Will the NIH continue to consider CoC requests for non- federally funded research?
Yes, NIH will continue to consider requests for specific projects in accordance with the current NIH policy for issuing CoCs. In these situations, the investigator must actively apply for a certificate

What do investigators need to do for research funded by NIH after October 1, 2017 with regards to the CoC?
As of October 1, 2017, for any new protocol funded in whole or in part by the NIH that meets the criteria for a certificate of confidentiality, investigators must include a statement about the certificate in the informed consent document. If a protocol is approved with a waiver of informed consent a CoC is still granted by NIH. However, there is no consent document to inform subjects. If verbal or another method of consent is obtained, this information must be communicated to the potential subject as part of that process. The IRB will make all efforts to assure the required statement is included in the consent forms. However, all investigators must take responsibility for including this information when submitting their consent documents to the IRB.

Is there template language to include in the consent?
Yes, the following language should be inserted:

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information that may identify you, even under a court order or subpoena unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or if it is used for other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in your medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

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How will BCH implement the policy retroactively to NIH funded research commenced or ongoing on or after December 13, 2016?

We have received clarification that NIH will allow the transition to the new requirement for consent statements at the time a protocol undergoes continuing review. The IRB office will insert the required language at the time of continuing review. IRB staff may be contacting you at the time of a continuing review to clarify the funding status of your research. After the language is inserted the revised consent form must be used for all subsequent subjects.

Investigators have the option to submit an amendment at any time before continuing review to revise the consent or include this change as part of any other amendment.

Please be sure protocols are continually updated to include the most current funding source. This will be the only way the IRB will be aware that the research is NIH funded.

NIH does not expect participants consented prior to the issuance of a Certificate, to be re-contacted to be informed of the Certificate since this is an added protection and subjects already consented to participate without the certificate.

Does a Certificate protect all identifiable, sensitive information collected or used during the duration of a research project?

For NIH funded research, a Certificate protects the information that was collected or used during the period in which the research is funded by NIH. If the study continues after NIH funding ends and you need continued protection of a Certificate for new information, you need to apply for a Certificate following the process for non-federally funded research. You may want continued protection, for example, if you were collecting new information from participants or enrolling new participants after the period in which the research was funded by NIH. If you continue with the same research after NIH funding, the consent would need to be revised to remove information about the CoC unless you apply and are granted a new certificate. Note that information protected by a Certificate, is protected in perpetuity, even after the research is no longer funded by NIH.

If a research project was issued a Certificate and continues under a no-cost extension, the research is considered to continue to be covered by the Certificate for the duration of the no-cost extension.

The staff of the Office of Sponsored Programs (osp@childrens.harvard.edu) and the IRB analyst assigned your department/division are also available to answer any questions you may have.