

Frequently Asked Questions regarding Certificates of Confidentiality for NIH-funded studies

On October 1, 2017 NIH updated its Certificates of Confidentiality (CoC) policy. Under this policy, CoCs will apply to ALL NIH-funded studies that collect identifiable data or biospecimens or generate human genomic data. The Einstein IRB has created this FAQ to help the research community. The NIH also has an FAQ here: <https://humansubjects.nih.gov/coc/faqs>.

What does this mean?

All NIH-funded studies with identifiable data (or biospecimens or that generate human genomic data) **automatically** receive a Certificate of Confidentiality as of October 1st, 2017.

Who does this affect?

Any NIH-funded study that collects identifiable data (or biospecimens or that generate human genomic data).

I don't have an NIH-funded study. Do I need to do anything?

The new Certificate of Confidentiality requirement only affects NIH-funded studies. If you do not have NIH funding, you do not need to do anything at this time. If you do not have NIH funding and would like to apply for a Certificate, consult the Einstein policy and guidance for more information.

What is the link for the new policy and guidance?

<https://www.einstein.yu.edu/docs/administration/institutional-review-board/policies/certificate-of-confidentiality.pdf>

What do I need to do if I am affected by the new NIH policy?

Review the policy to familiarize yourself with the confidentiality measures provided by a Certificate of Confidentiality.

For new studies with consent documents (including studies with oral consent), you must add the Certificate of Confidentiality language (it's in our consent template).

For existing studies that are still enrolling subjects, you must add the following language to your templates (under the Confidentiality section):

Certificate of Confidentiality

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

For studies that are closed to enrollment, you do not need to update your consent documents.

Do you have a Spanish translation of the Certificate of Confidentiality Language?

Yes.

Certificado de confidencialidad

Con el fin de proteger su privacidad, hemos obtenido un certificado de confidencialidad de los Institutos Nacionales de la Salud de los Estados Unidos (National Institutes of Health), que es la que financia este estudio. Si la información de este estudio fuera solicitada u ordenada por una orden judicial por las agencias del gobierno o las cortes, usaremos este certificado para legalmente negarnos a proporcionar tal información. Esto es una situación poco probable - solamente en unas pocas ocasiones, los investigadores tuvieron que usar el certificado, y se respetó la mayor parte del tiempo, pero no siempre. Existen varios tipos de situaciones en las que el certificado no es aplicable. Sin embargo, se nos exige, por ejemplo, denunciar abuso infantil y algunas enfermedades, y debemos poner a disposición del gobierno la información para un análisis o una evaluación de nuestra investigación. El certificado de confidencialidad no le impide a usted o a un familiar suyo compartir información de manera voluntaria. De manera similar, si una compañía de seguros, empleador u otra persona obtiene su autorización por escrito para recibir información sobre la investigación, entonces los investigadores no pueden usar el certificado de confidencialidad para no entregar esa información.

Do I need to use a certified translator to add this language to my Spanish consent document(s)?

No, as long as this is the only update that you are making.

My consent document already has Certificate of Confidentiality language in it. Do I need to update the language to match the current template?

No.

I have already enrolled subjects in my study, do I need to reconstent them?

No. However, you must review the policy

(<https://www.einstein.yu.edu/docs/administration/institutional-review-board/policies/certificate-of-confidentiality.pdf>) to familiarize yourself with the confidentiality measures provided by a Certificate of Confidentiality.

My study is closed to enrollment, do I need to add the language to the consent document?

No. However, you must review the policy

(<https://www.einstein.yu.edu/docs/administration/institutional-review-board/policies/certificate-of-confidentiality.pdf>) to familiarize yourself with the confidentiality measures provided by a Certificate of Confidentiality.

I am collecting data from subjects in a foreign country under an NIH-funded study. Will my research be issued a Certificate of Confidentiality?

Certificates will be issued to recipients for NIH-funded research regardless of the country where the investigator or the protected information resides. However, Certificates may not be effective for data held in foreign countries.

If you believe that the Certificate of Confidentiality will not protect data held in foreign countries from legal demand within that country consult with your foreign collaborators and bring this information to the attention of the Einstein IRB.

Please contact the Einstein IRB at irb@einstein.yu.edu if you have questions about this new requirement or about amending your consent documents to meet this requirement.