Consent Language for Certificates of Confidentiality (CoC) Automatically Issued as a result of the NIH CoC Policy Change

NIH CoC Policy Change:

Effective October 1, 2017, the National Institutes of Health (NIH) updated its policy for issuing Certificates of Confidentiality (CoC) to automatically cover applicable studies rather than require an application process to request a CoC. NIH funded studies that were ongoing or started after December 13, 2016 that collect “identifiable, sensitive information” from subjects, are now deemed to have a Certificate of Confidentiality.

NIH Studies Affected:

The NIH provides criteria for investigators to determine if NIH funded research is automatically covered by a CoC. If unsure, investigators should consult the NIH CoC FAQs for descriptions of identifiable, sensitive information. For questions not addressed on the FAQ, contact the NIH Office of Extramural Research: NIH-CoC-Coordinator@mail.nih.gov.

CoC and NIH Expectations for Informed Consent:

For studies with informed consent, that are deemed to have a CoC per the new policy, the NIH expects investigators to inform research participants of the protections and the limits to protections provided by the CoC. The UK IRB Informed Consent templates contains sample CoC language to include when applicable.

To add CoC language to an existing consent document, submit a Modification Request for the applicable protocol. Indicate on the Modification Request form, whether the CoC information might relate to a subject’s willingness to continue participation given the context of the research.

Additional CoC Information:

For additional information on Certificates of Confidentiality, see ORI COC summary at http://www.research.uky.edu/ori/human/56-ORI_Summary_on_COC.pdf
Choosing the Correct Study Personnel in E-IRB

Is it this John Smith or that John Smith?

When adding Study Personnel to your protocol application, make sure that you are choosing the correct individual. There may be several individuals within the Study Personnel Table by the same name.

Before selecting the individual that you wish to add to your protocol application, you will need to check the ADAccount (Link Blue ID) and the PersonID (UK Employee ID) to ensure that the information matches your John Smith.

The ADAccount (Link Blue ID) will state “NonUK” and the PersonID will start with the letter N. In this case you may need to match the email address with the correct individual if there is more than one Non-UK person by the same name.