IRB SOP 1205
Certificate of Confidentiality

Purpose

This Standard Operating Procedure (SOP) describes procedures to request a federal Certificate of Confidentiality (Co-3.7 (t)0 3102 (3 1 <<-6.6 (EMC /.3 (3 1 <ralit)7.(yF43 (i (ajm)4.7t)0 102)01.72 551./.3 (3 1 <r

Policy

The NIH Policy on Certificates of Confidentiality (CoC) applies to “

” that was commenced or ongoing after December 13, 2016.

If a NIH-funded activity falls within the scope of the NIH policy, CoCs are automatically granted as part of terms and conditions of the award and the requirements of such must be complied with. Investigators and institutions are responsible for determining when a NIH-funded activity falls within the scope of the NIH policy and if the CoC is included as part of the terms and conditions of the award.

NIH policy expands upon 42 U.S.C. 241(d) by explaining that NIH considers research in which identifiable, sensitive information is collected or used, to include:

> Human subjects research as defined in 45 CFR 46, including research determined to be exempt (except for exempt research when the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects);

Procedure

1.0 For NIH-funded studies in which a CoC has been issued:

1.1 Investigators are responsible for clearly representing in the IRB submission that a CoC is in place (e.g. as terms and conditions of an NIH award).

1.2 When reviewing research under a CoC, the IRB will evaluate whether the research protocol is consistent with the obligations to protect information and specimens under a CoC and whether the consent language, if applicable, discloses the CoC and appropriately describes the associated protections and limitations.

1.4 Sample consent language is provided by the IRB or the sample language describing the CoC protections may be used.

2.0 For all other HHS-funded (non-NIH) research, all other federal agency funded research, and non-federally funded research or when the IRB requests a CoC:

2.1 Investigators are responsible for clearly representing in the IRB submission that a CoC is in place, if a CoC application is pending, or that an application for a CoC hasbeen submitted. When the CoC application is in process or Ht (e)3 (n)10 g3 (n) (C.1

References

NIHCertificates of Confidentiality
NIH Sample Consent Language for Certificate of Confidentiality