HRP-333 | 3/29/2024

WORKSHEET: Certificate of Confidentiality

The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating whether a Certificate of Confidentiality is required or appropriate for a study.[[1]](#endnote-2)

1. Considerations for Certificate of Confidentiality (Check if “Yes”)

The research is funded by the National Institutes of Health (NIH) and is biomedical, clinical, or other research.[[2]](#endnote-3) If “**Yes**,” a COC is automatically issued through the award. Other HHS agencies provide a CoC for funded research upon request.[[3]](#endnote-4)

The research is health-related biomedical, behavioral, clinical, or other research that is not funded by HHS.[[4]](#endnote-5)

If “**Yes**,” answer the following:

The research is collecting personally identifiable information.

The research is sensitive.[[5]](#endnote-6)

The research is collecting information that if disclosed could significantly harm or damage the participant.

1. Certificate of Confidentiality for Research Language is included in Consent (If “Yes” in #1, must be “Yes”)

The consent document includes information describing the CoC and its purpose and its applicability to the research.[[6]](#endnote-7)

1. This document satisfies AAHRPP element II.3.E [↑](#endnote-ref-2)
2. NOT-OD-17-109: Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality; <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html> [↑](#endnote-ref-3)
3. To identify appropriate HHS agency for CoC request; <https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm#step1> [↑](#endnote-ref-4)
4. Online Certificate of Confidentiality System; <https://public.era.nih.gov/commonsplus/public/coc/request/init.era> [↑](#endnote-ref-5)
5. Examples of sensitive research activities include but are not limited to the following: collecting genetic information; collecting information on psychological well-being of subjects; collecting information on subjects’ sexual attitudes, preferences, or practices; collecting data on substance abuse or other illegal risk behaviors’ studies where subjects may be involved in litigation related to exposures under study (e.g., breast implants, environmental or occupational exposures). [↑](#endnote-ref-6)
6. NIH-funded research conducted internationally and meeting the above criteria will still be considered to have been issued a COC, however the enforceability of the COC is uncertain if the data are held in foreign jurisdictions. For these studies, the consent should include a statement regarding this uncertainty. [↑](#endnote-ref-7)