HRP-333 | 12/4/2024

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.

1. **Additional Considerations for Studies where a Certificate of Confidentiality is Required or Appropriate** (If “Yes” in #1, must be “**Yes**”)

The research will not utilize third parties or entities to collect or store information (e.g., contractors, online platform vendors) that cannot or will not protect against the compelled disclosure of the personally identifiable information.[[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. Institutional Assurance Statement; <https://grants.nih.gov/policy/humansubjects/coc/required-institutional-assurances.htm>; Investigator and Institutional CoC Responsibilities - 3. Uphold CoC protections.<https://grants.nih.gov/policy/humansubjects/coc/information-institutional-responsibilities.htm> [↑](#endnote-ref-7)