



HRP-333 | 1/1/2024

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.ⁱ

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.ⁱⁱ If “Yes,” a CoC is automatically issued through the award. Other HHS agencies provide a CoC for funded research upon request.ⁱⁱⁱ
- The research is health-related biomedical, behavioral, clinical, or other research that is not funded by HHS.^{iv}
If “Yes,” answer the following:
 - The research is collecting personally identifiable information.
 - The research is sensitive.^v
 - The research is collecting information that if disclosed could significantly harm or damage the participant.

2. 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.

ⁱ This document satisfies AAHRPP element II.3.E

ⁱⁱ 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>

ⁱⁱⁱ To identify appropriate HHS agency for CoC request; <https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm#step1>

^{iv} Online Certificate of Confidentiality System; <https://public.era.nih.gov/commonsplus/public/coc/request/init.era>

^v 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).