HRP-333 | 10/18/2023

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).