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

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 If “Yes,” a COC is automatically issued through the award. Other HHS agencies provide a CoC for funded research upon request.³

☐ The research is health-related biomedical, behavioral, clinical, or other research that is not funded by HHS.⁴

If “Yes,” answer the following:

☐ The research is collecting personally identifiable information.

☐ The research is sensitive.⁵

☐ 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.

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¹ This document satisfies AAHRPP element II.3.E
³ To identify appropriate HHS agency for CoC request; https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm#step1
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).