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| The purpose of this worksheet is to provide support for the convened IRB, Chair, Vice-Chair, or designee when evaluating whether a Certificate of Confidentiality is required or appropriate for a study. [[1]](#endnote-1) This worksheet is to be used. It does not have to be completed or retained. |
|  |
| 1. Considerations for Certificate of Confidentiality (Check if “Yes”.)
 |
| [ ]  | The research is funded by the National Institutes of Health (NIH) and is biomedical, behavioral, clinical, or other research. [[2]](#endnote-2) If **“Yes,”** a CoC is automatically issued through the award.Other HHS agencies provide a CoC for funded research upon request. [[3]](#endnote-3) |
| [ ]  | The research is health-related biomedical, behavioral, clinical, or other research that is not funded by HHS. [[4]](#endnote-4)  |
|  | If **“Yes”,** answer the following: |
|  | ☐ | The research is collecting personally identifiable information. |
|  | ☐ | The research is sensitive. [[5]](#endnote-5) |
|  | ☐ | 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. This document satisfies AAHRPP element II.3.E [↑](#endnote-ref-1)
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-2)
3. To identify appropriate HHS agency for CoC request; <https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm#step1> [↑](#endnote-ref-3)
4. Online Certificate of Confidentiality System; <https://public.era.nih.gov/commonsplus/public/coc/request/init.era> [↑](#endnote-ref-4)
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-5)