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| 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. This worksheet is to be used. It does not have to be completed or retained. | | |
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| 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.[[1]](#endnote-1) If **“Yes,”** a CoC is automatically issued through the award.Other HHS agencies provide a CoC for funded research upon request. [[2]](#endnote-2) | |
|  | The research is health-related biomedical, behavioral, clinical, or other research that is not funded by HHS. [[3]](#endnote-3) | |
|  | If “**Yes**,” answer the following: | |
|  | ☐ | The research is collecting personally identifiable information. |
|  | ☐ | The research is sensitive.[[4]](#endnote-4) |
|  |  | 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. Reference the Social Behavioral Consent Document template (HRP-582) or the Biomedical Consent Document template (HRP-592) for sample consent language that should be used when describing the protections, limitations and exceptions afforded by the Certificate. | |
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1. 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-1)
2. To identify appropriate HHS agency for CoC request; <https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm#step1> [↑](#endnote-ref-2)
3. Online Certificate of Confidentiality System; <https://auth.nih.gov/iTrustGateway/Default.aspx?TYPE=33554433&REALMOID=06-5807c3f7-b083-45f1-adb1-db80ca5cb984&GUID=&SMAUTHREASON=0&METHOD=GET&SMAGENTNAME=-SM-jeABPYEu%2fp%2bemXLDSAj1EOFiRlGv9qfbJmuw7fe6Wig0qkH%2bz5BoOZgj%2f4Q0KTjg&TARGET=-SM-HTTPS%3a%2f%2fcoc%2eod%2enih%2egov%2f> [↑](#endnote-ref-3)
4. 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-4)