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| **Version History** | **Date** | **Revision** |
| R00 | 9/30/17 | Original issue |
| R00 | 12/11/20 | Annual review, no changes |
| R01 | 1/17/23 | Annual review, fixed grammatical error |
| R01 | 11/16/23 | Annual review, no changes |

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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-2) If **“Yes,”** a CoC is automatically issued through the award.Other HHS agencies provide a CoC for funded research upon request. [[2]](#endnote-3) | |
|  | The research is health-related biomedical, behavioral, clinical, or other research that is not funded by HHS. [[3]](#endnote-4) | |
|  | If “**Yes**,” answer the following: | |
|  | ☐ | The research is collecting personally identifiable information. |
|  | ☐ | The research is sensitive.[[4]](#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. | |
| The Following are examples of suggested consent language for research with a CoC:  This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot  release or use information, documents or samples that may identify you in any action or suit unless you say it is okay. They cannot provide  them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other  proceeding.  There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws  require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself  or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records  or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The  Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.  Researchers may release information about you when you say it is okay. For example, you may give them permission to release information  to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you  from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own  information.[[5]](#endnote-6)    [Note: For studies that were previously issued a CoC and subjects were notified of the protections provided by that Certificate, NIH does not  expect subjects to be notified that the protections afforded by the Certificate have changed, although the IRB may determine whether it is  appropriate to inform subjects.  If part of the study cohort was recruited prior to issuance of the certificate, but are no longer actively participating in the study, NIH does not  expect subjects consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections  afforded by the Certificate have changed, or that subjects who were previously consented to be re-contacted to be informed of the  Certificate, although IRBs may determine whether it is appropriate to inform subjects.] | | |
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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>. Examples of research automatically covered by a Certificate of Confidentiality include: (1)Biomedical, behavioral, clinical or other research, including exempt research, except where the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (2) The collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual; (3) The generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained;(4) Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual. [↑](#endnote-ref-2)
2. To identify appropriate HHS agency for CoC request; <https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm#step1> [↑](#endnote-ref-3)
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-4)
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-5)
5. [https://grants.nih.gov/policy/humansubjects/coc/helpful-resources/suggested-consent.htm](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.nih.gov%2Fpolicy%2Fhumansubjects%2Fcoc%2Fhelpful-resources%2Fsuggested-consent.htm&data=05%7C01%7Cjmsmith%40buffalo.edu%7Ca3b5b9bfca1047bf24e808dadd7c26f8%7C96464a8af8ed40b199e25f6b50a20250%7C0%7C0%7C638065822707706636%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000%7C%7C%7C&sdata=ZyUI8up65kyFaQapq4nb9ktZOn5NHHmXoi8rC3sM40A%3D&reserved=0) [↑](#endnote-ref-6)