1.0 Purpose:

1.1 The purpose of this policy is to outline the process for obtaining a Certificate of Confidentiality (CoC) to further protect the confidentiality of human subjects participating in research that may be collecting sensitive information.

2.0 Definitions:

2.1 Identifying characteristic - any characteristic such as name, address, social security or other identifying number, fingerprints, voiceprints, photographs, genetic information or tissue samples, or any other item or combination of data about a research subject that could reasonably lead, directly or indirectly by reference to other information, to identification of that research subject.

2.2 Sensitive Information - any information which could be of interest to the court in civil, criminal or other judicial proceedings. Examples include: use of alcohol, illegal drugs or addictive products and illegal behavior.

2.3 Significant Change - any major change in the scope or aim of the research protocol, change in personnel having major responsibilities in the project, or change in the drugs being administered (if any) and the persons who will administer.

3.0 Background:

3.1 CoCs are issued by the federal government [NIH, FDA and other Department of Health and Human Services (DHHS) agencies] to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Protection against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research is provided by the Public Health Service Act §301(d), 42 U.S.C. §241(d).

3.2 The certificate adds an additional level of protection for maintaining confidentiality of private information. Without the certificate, researchers can be required by a court-ordered subpoena to disclose research results (usually as part of a criminal investigation of the subjects). Any research project that collects personally identifiable, sensitive information and has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for a Certificate.

3.3 CoCs may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. Separate applications are generally required for each research project for which a Certificate is desired. However, projects that use the same sample of subjects but have different protocols may file for one Certificate since the subjects, whose identities the investigator wishes to protect, are the same.

3.4 Any person engaged or who intends to engage in research in which sensitive information is gathered from human research participants may apply for a Certificate of Confidentiality (CoC). Individuals who participate as research subjects in the specified project during any time the Certificate is in effect are protected permanently. If the IRB allows enrollment prior to receipt of the CoC, study subjects
Certificates of Confidentiality are not protected until the CoC is issued. Once the CoC is issued, all information given to researchers is protected including any that was given prior to issuance.

3.5 Any investigator engaged in research in which sensitive information is gathered from human subjects (or any person who intends to engage in such research) may apply for a Certificate of Confidentiality. Research is considered "sensitive" if it involves the collection of information such as sexual attitudes, preferences, practices; personal use of alcohol, drugs, or other addictive products; illegal conduct; and information that could damage an individual's financial standing, employability, or reputation within the community etc. Personally identifiable information protected by a Certificate may be disclosed under the following circumstances:

3.5.1 Voluntary disclosure of information by study participants themselves or any disclosure that the study participant has consented to in writing, such as to insurers, employers or other third parties;

3.5.2 Voluntary disclosure by the researcher of information on such things as child abuse, reportable communicable diseases, possible threat to self or others, or other voluntary disclosures that are spelled out in the informed consent form;

3.5.3 Voluntary compliance by the researcher with reporting requirements of state laws, such as knowledge of communicable disease, provided such intention to report is specified in the informed consent form; or

3.5.4 Release of information by researchers to DHHS as required for program evaluation or audits of research records or to the FDA as required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301.)

3.6 Certificates of Confidentiality do not prevent other types of intentional or unintentional breaches of confidentiality. It is imperative that other appropriate mechanisms and procedures are in place to protect the confidentiality of identifiable private information that is obtained in the proposed research.

3.7 If the research is conducting a sensitive research project that is covered by the Agency for Healthcare Research and Quality (AHRQ) confidentiality statute (42 U.S.C. section299a-1(c) entitled “limitation on use of certain information”) or the Department of Justice confidentiality statute (42USC section 3789g), then a CoC is not required.

4.0 Procedure:

4.1 An application for a CoC is, generally, submitted after the IRB approves the research since IRB approval or approval conditioned upon issuance of a CoC is a prerequisite for issuance. Since the informed consent needs to include language describing the Certificate and any voluntary disclosures specified by the investigator, the investigator must inform the IRB that they are applying for a CoC and have included appropriate language in the informed consent.

4.2 The IRB may determine that a study can commence concurrent with the investigator applying to the appropriate federal agency for the CoC or it may require that no subjects be enrolled until the investigator has obtained a CoC. This is dependent on the need for the protection offered by the CoC in relation to the type of sensitive information being collected.
4.3 The application for a Certificate of Confidentiality is to be written on the letterhead of the research applicant institution and submitted to the appropriate DHHS agency involved in the funding or regulation of the study. For studies that are not funded by DHHS, investigators should select the DHHS agency that most closely relates to the research area of the study. (Websites noted in the references provide current contact information and addresses.)

4.4 The application and approval process may take up to three months.

4.5 The application must include:

4.5.1 Name and address of applicant research institution. This is the institution with which the applicant is affiliated and the recipient of grant support for the research, if any.

4.5.2 Name, title, mailing, and email addresses, telephone and fax numbers of the applicant as well as the name and title of other key personnel. Include brief summary of the relevant training and experience and/or curriculum vitae of the applicant and key personnel.

4.5.3 Title of the research project. If the project title on the Institutional Review Board (IRB) form is different from the title given here, the applicant must document that the approval pertains to this project.

4.5.4 Source and number of the supporting grant, if applicable (e.g., "This research is supported by SPNS Grant BRH-xxxxxx from the Health and Human Resources Services Administration."). If none, state "This study is not supported by Federal funds.

4.5.5 Name and location where the research will be conducted and a brief description of the facilities available for the conduct of the research. Indicate if this is a multi-site project. The lead site of a multi-site project should apply for a single Certificate to protect participants at all sites. The multi-site applicants must list each participating unit, its address and project director. If a new site is added after the certificate is issued, the lead site should provide the applicable agency with an updated list. The cover letter should include a statement by the lead site that IRB approval has been given at the new site and that the lead site is maintaining a copy of that approval.

4.5.6 A CoC will not be issued unless the project has IRB approval. The approving IRB must be in compliance with applicable Federal requirements. If the applicant institution is receiving DHHS funding for research involving human subjects, an OHRP approved IRB for that institution must approve the project for which a CoC is sought.

4.5.6.1 Documentation of IRB approval: Approval must be current and unconditional, or conditional only upon the issuance of a Certificate of Confidentiality and documented by an attached letter or form signed by an authorized IRB representative.

4.5.6.2 Documentation of IRB qualifications: For all projects, submit for the IRB that reviewed the project the Federalwide Assurance number assigned by OHRP or documentation that the IRB
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complies with the applicable Federal regulations governing research involving human subjects. (Hartford HealthCare’s Federalwide Assurance Number is FWA00000601.) If this is a multi-site project, the lead site must maintain the OHRP assurance number for the reviewing IRB at each site, which must be available to the issuing agency upon request.

Note: If the applicant institution does not receive DHHS funding for this research, but has an IRB that complies with the requirements for IRBs imposed by another federal agency, that IRB must approve the research. If the applicant institution does not have an IRB, the project should be reviewed by an IRB in accordance with 45 CFR Part 46.

4.5.7 Beginning and expected end dates of the project. The CoC will state the date upon which it becomes effective and the date upon which it expires. A CoC protects all information identifiable to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the certificate is in effect. The protection afforded by the Certificate is permanent.

4.5.8 Concise description of the project aims and research methods (1-2 paragraphs, omit background). Include the number, source and description of the human subjects. If significant changes are made to the project aims or methods during the course of the study, the applicant should contact the Certificate coordinator who issued the Certificate. The coordinator will determine if the Certificate can be modified or if the applicant will need to submit an amended application.

4.5.9 Concise description of the means used to protect subjects’ identities (e.g., coded identifiers, record access restricted to trusted staff, locked files and secured data storage, etc.).

4.5.10 Justification for requesting a CoC (e.g., will collect sensitive information, identifying information on subjects, etc.). Include a brief description of the sensitive and identifying information to be collected.

4.5.11 Attach copies of the informed consent forms to be used in the study, as approved by the IRB. The informed consent must include a description of the protections and limitations of the CoC, including the circumstances in which the investigators plan to disclose voluntarily identifying information about research participants (i.e., child abuse, harm to self or others, etc.). If this is a multi-site project, the lead site must indicate that it has a copy on file of the consent form as approved by the IRB from each site, which will be made available to issuing agencies upon request. The sample language that follows may be modified as necessary:

4.5.11.1 “A Certificate of Confidentiality (CoC) has been [applied for/obtained] from the Federal Government for this study to help insure your privacy. This Certificate means that the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or other proceedings. But, if you request disclosure, we can release the information.”
4.5.11.2 “This protection will not be in effect until we have obtained the CoC, which may take a few months. You will be informed when the CoC has been received.”

4.5.11.3 “If you decide to take part in this research study, you will be required to give us information about your [substance use/genetic information/criminal behavior, etc]. Any of your identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission, with the following exceptions: We will disclose to appropriate authorities reportable diseases, known or suspected abuse of a child or elderly person, or if you become a danger to yourself or others.”

4.5.11.4 “The certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).”

4.5.11.5 “You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.”

4.5.11.6 “When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.”

4.5.12 Research not funded by NIH in which drugs will be administered to human subjects must provide the following additional information:

4.5.12.1 Identification of drugs to be administered;

4.5.12.2 Description of methods for administration of these drugs, including a statement of dosages;

4.5.12.3 Evidence that individuals who will receive the drugs are authorized to do so under applicable Federal and State law.

4.5.13 All research in which a controlled drug or drugs will be administered must submit a copy of the Drug Enforcement Administration Certificate of Registration (BND Form 223) under which the research project will be conducted.

4.5.14 If the research project is testing for reportable communicable diseases, the applicant must submit information relating to its compliance with State reporting laws as specified in the August 9, 1991 memorandum from the Assistant Secretary for Health – Certificates of Confidentiality – Disease Reporting.
4.5.15 All agencies that grant CoCs require that assurance language be included in the application. Although the language is similar, each agency requires that the language be _verbatim_ as defined in the application. Review the instructions from the applicable agency and insert the assurance that is required. The following assurance information is from the NIH:

4.5.15.1 “This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges.”

4.5.15.2 “The institution and personnel involved in the conduct of the research will comply with the applicable Federal regulation for the protection of human subjects or, if no such Federal regulation is otherwise applicable, they will comply with 45 CFR Part 46.”

4.5.15.3 “This Certificate of Confidentiality will not be represented as an endorsement of the project by the DHHS or NIH or used to coerce individuals to participate in the research project.”

4.5.15.4 “All subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate.”

4.5.15.5 “Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.”

4.5.16 Both the principal investigator and the Institutional Official must sign the application letter. The name, title and address of the Institutional Official are to be typed below the signature.

4.6 Upon receipt of the CoC, submit a copy to the IRB and inform all subjects already enrolled that the protection offered by the CoC is now in effect. Update research records to note that subjects were informed. Subjects who are no longer actively participating in the research may be informed by mail with a copy of the letter retained in the research file.

4.7 Submit an amendment to the IRB along with revised consent documents that are modified to say that the CoC is _obtained_.

4.8 Protocol amendments must be submitted to the IRB for any changes to an approved protocol prior to implementation.

4.9 If a significant change to the research project is proposed after issuance of a CoC, the investigator must inform the issuing agency by submitting an amended application. Instructions and forms for filing an amended CoC application are the same as the original CoC application. The IRB approval documentation of the amendment would need to be included.

4.10 The researcher is responsible to ensure that the CoC remains valid. If a study’s duration needs to be extended, and data collection will continue past the expiration date of the CoC, the researcher must submit a written request to the appropriate agency for an extension of the CoC expiration date at least 3 months prior to the
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expiration date. Extension applications should include a rationale for the extension request, a revised estimate of the study duration, the most recent IRB approval of the study, and a copy of the approved consent form which states a CoC has been obtained.

5.0 Documentation:

5.1 The HHC HRPP office maintains all records related to the implementation of this policy, electronic communications, and notifications to investigators, funding or regulatory agencies, etc.

5.2 Records are archived for a period of at least six (6) years following the termination or completion of the research activities.

6.0 References:

6.1 Public Health Service Act §301(d), 42 U.S.C. §241(d): Protection of privacy of individuals who are research subjects

6.2 45 CFR Part 46: Protection of Human Subjects

6.3 Guidance on Certificates of Confidentiality, February 25, 2003

6.4 Certificate of Confidentiality Kiosk, Office of Extramural Research (NIH) application information: http://grants.nih.gov/grants/policy/coc/

6.5 U.S. Department of Health and Human Services, Health Resources and Services Administration application information: http://www.hrsa.gov/humansubjects/certificates.htm


7.0 Revision History:

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<tr>
<th>Rev #</th>
<th>Initials</th>
<th>Effective Date</th>
<th>Description of Change(s)</th>
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<tr>
<td>01</td>
<td>PMJ/EHP</td>
<td>7/1/11</td>
<td>Conversion to new policy template; significant expansion of policy</td>
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Element II.3.E.