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| **Instructions** | | | | |
| * This form is completed by the Michigan State University Principal Investigator (PI) if the study is subject to a Certificate of Confidentiality (CoC) based on funding or an application will be submitted to apply for a CoC. * CoCs protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research with limited exceptions. * NOTE: “Identifiable, sensitive information” means information that is about an individual and that is gathered or used during the course of research and—    + (A) through which an individual is identified; or   + (B) 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. * **NOTE: THIS FORM MUST BE COMPLETED AND UPLOADED BY THE PI**. The PI of a study that is protected by a CoC is responsible for assuring that CoC requirements are followed. * Click™ IRB   + Include the template with a New Study Submission or a Modification. | | | | |
| **Complete Questions 1 – 5.** | | | | |
| 1 | Study title. Click or tap here to enter text. | | | |
| 2 | Name of Principal Investigator. Click or tap here to enter text. | | | |
| Complete 2A. **THIS FORM MUST BE COMPLETED AND SUBMITTED BY THE MSU PI.** | | | |
| 2A | By checking the boxes, I acknowledge that: | | | |
|  | | | The PI is completing this form and providing all acknowledgements. |
|  | | | As PI, I am responsible for assuring that CoC requirements are followed and for assuring that all study team members are aware of and are trained on the CoC protections. |
| 3 | Is or will this study be sponsored by an external entity?  No  Yes | | | |
| If you answered YES, complete 3A, 3B, and 3C. | | | |
| 3A | Indicate the source of the external funding that is or may be associated with this activity, including pending or future proposals. If you are receiving a subcontract, indicate both the primary and direct funding sources. | | | |
|  | | | U.S. Health and Human Services, select option(s) below: |
|  | | | Agency for Healthcare Research and Quality, NOTE: CoCs are not typically issued for studies funded by AHRQ because the AHRQ has their own privacy requirements. |
|  | | | Centers for Disease Control and Prevention |
|  | | | Health Resources & Services Administration |
|  | | | Indian Health Service |
|  | | | National Institutes of Health |
|  | | | Substance Abuse and Mental Health Service Administration |
|  | | | Other Health and Human Services agency, describe: Click or tap here to enter text. |
|  | | | U.S. Department of Justice, NOTE: CoCs are not issued for studies funded by DOJ because the DOJ has their own privacy regulations. |
|  | | | Other U.S. Federal Agency, describe: Click or tap here to enter text. |
|  | | | Other External Sponsor, describe: Click or tap here to enter text. |
| 3B | What is the status of the funding source(s)? Select all that apply.  Awarded  Just in Time  Proposal submitted to funding agency  Other, please explain: Click or tap here to enter text. | | | |
| 3C | Are any of the funds being received through a subcontract?  No  Yes | | | |
| 4 | Will you be applying for a CoC? NOTE: NIH and CDC funded research are AUTOMATICALLY issued a CoC and researchers do not apply for a CoC.  No  Yes  Unsure | | | |
| If you answered YES or UNSURE, complete 4A. | | | |
| 4A | By checking the boxes, I acknowledge | | | |
|  | | | I will work with the MSU HRPP to prepare the CoC application. |
|  | | | I cannot sign the CoC application as the Institutional Official. |
|  | | | I will notify the HRPP of the status of the CoC once a determination is made (issued, not issued). |
|  | | | If the CoC is issued, I will provide a copy of the CoC through an IRB submission (e.g., part of the new study submission if not yet approved or as a modification). |
|  |  | | | The protection afforded by a CoC may not extend to significant changes in the study after a CoC is issued. I will contact the HRPP if significant changes are being proposed to determine if an updated CoC is required. |
|  |  | | | I understand that the IRB may determine that enrollment of subjects isn’t permitted until a CoC is issued or it is determined that a CoC won’t be issued. |
| 5 | Research will be conducted:  Within the United States  Michigan  Outside of Michigan, please describe: Click or tap here to enter text.  Internationally (outside the United States), please identify the country(ies): Click or tap here to enter text. | | | |
| NOTE: For studies that are submitting an application for a CoC, if data are maintained ONLY in the foreign country, a CoC may not be effective and will generally not be issued by NIH. | | | |
| **Data Sharing. Complete Questions 6 – 8.** | | | | |
| 6 | Will any subject information be shared with any investigator or institution beyond the MSU study team for this study? For example, institutional collaborators, consultants, temporary contractors, subrecipients, etc.  No  Yes | | | |
| If you answered YES, complete 6A and 6B. | | | |
| 6A | Describe who the subject information will be shared with: Click or tap here to enter text. | | | |
| 6B | Check the boxes to acknowledge to assure that: | | | |
|  | | Any investigator or institution who receives a copy of information protected by a CoC will be informed that they are also subject to the requirements of the CoC. | |
|  | | Any collaborators that are carrying out part of the research study involving a copy of information protected by the CoC understand that they are subject to the CoC requirements. | |
| 7 | Does or will MSU submit the CoC application on behalf of non-MSU investigators or institutions? NOTE: NIH and CDC funded research are AUTOMATICALLY issued a CoC and do not apply for a CoC.  No  Yes | | | |
| If you answered YES, complete 7A. | | | |
| 7A | Check the boxes to acknowledge that as the lead site for the CoC, the MSU PI will assure that the following are performed. | | | |
|  | | | Maintain a list of all performance sites, including addresses and project direct names. The lead site should maintain a current list of all performance sites, addresses and project director names. |
|  | | | Obtain signed assurances from each participating institution. These should be kept by the lead institution and made available by request. |
|  | | | Is responsible for ensuring that each site’s consent forms contain appropriate language describing the CoC and should work with the IRB to review consent form language. |
|  | | | Provide a copy of the CoC to each participating institution after the CoC has been issued. |
|  | | | Develop appropriate agreements with the participating institutions to implement the CoC requirements. |
|  | | | If MSU is requested to serve as the lead site for a CoC application, MSU has the discretion to decline to submit the CoC on behalf of all institutions. |
|  | | | Follow CoC requirements of the federal agency through which the CoC is being applied for. |
| 8 |  | | | Check the box to acknowledge that if a secondary researcher receives information from this study protected by a CoC, that the PI will assure that the secondary researcher is informed that the information that is disclosed to them is protected by a CoC, and that the secondary researcher is required to uphold the protection of the CoC. |
| **Complete CoC Acknowledgements 9 - 15. Read and Acknowledge the Information Below.** | | | | |
| 9 | Have you previously completed this form for another study and have already completed the CoC acknowledgements in this section?  No  Yes | | | |
| If you answered NO, complete 10-15.  If you answered YES, complete 9A. | | | |
| 9A |  | *ONLY COMPLETE THIS ACKNOWLEDGEMENT IF YOU ANSWERED YES TO QUESTION 9. YOU DO NOT NEED TO COMPLETE 10-15 AFTER PROVIDING THIS ACKNOWLEDGEMENT.* By checking the box, I acknowledge that I have completed the CoC acknowledgements for another study and I confirm that I will follow the acknowledgements for this study. | | |
| 10 | By checking the boxes, I acknowledge that: | | | |
|  | | | A CoC protects the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research with limited exceptions. |
|  | | | “Identifiable, sensitive information” means information that is about an individual and that is gathered or used during the course of research and— (A) through which an individual is identified; or (B) 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. |
| 11 | By checking the boxes, I acknowledge and assure that with the following requirements will be met: | | | |
|  | | | All recipients of a CoC shall NOT disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the re-search [except in the circumstances described in Acknowledgement 12 below] |
|  | | | All recipients of a CoC shall NOT In any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, disclose or provide the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the re-search [except in the circumstances described in Acknowledgement 12 below] |
| 12 | By checking the boxes, I acknowledge and assure that disclosure will only be made under the following circumstances: | | | |
|  | | | Disclosure is permitted only when required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding. |
|  | | | Disclosure is permitted only when necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual. |
|  | | | Disclosure is permitted only when made with the consent of the individual to whom the information, document, or biospecimen pertains. |
|  | | | Disclosure is permitted only when made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research. |
| 13 | By checking the boxes, I acknowledge that: | | | |
|  | | | Identifiable, sensitive information collected by a person to whom a CoC has been issued and all copies are subject the protections afforded by the CoC for perpetuity. The protection afforded by a CoC is permanent with respect to subjects who participated in research during any time the authorization was in effect. |
|  | | | If a researcher receives a request to release sensitive identifiable information that is not permitted under the CoC or if the researcher is unsure whether a release is permitted, the PI will contact the MSU Human Research Protection Program (HRPP). The HRPP will consult with the Office of the General Counsel. |
| 14 | By checking the boxes, I acknowledge the following: | | | |
|  | | | Subjects must be informed for any research in which informed consent is sought and will be informed that a CoC has been issued, and they will be given a description of the protection provided by the CoC and disclosures outside the scope of coverage of the CoC (e.g., public health reporting as required by Federal, State, or local laws, or requirements for child or elder abuse reporting). |
|  | | | CoC informed consent requirements apply to both exempt and non-exempt research. Informed consents for exempt research must include CoC information for the entire period where a CoC is in effect for the study. |
| 15 | By checking the boxes, I acknowledge the following: | | | |
|  | | A CoCs expiration depends upon how the CoC is issued (e.g., automatically issued, applied for). For NIH or CDC funded research, the CoC expires when the funding ends. For other research, the expiration date will be part of the application. If a CoC will be expiring and the PI plans to collect new data from research participants after the expiration, the PI will determine before the CoC expires whether to extend the CoC or to request a new CoC. | |
|  | | The PI is responsible for tracking the expiration of the CoC and any requests to update or file a new CoC should be submitted by the PI to allow adequate time to receive an updated or new CoC prior to the expiration of the current CoC. | |
|  | | If the PI decides not to extend or request a new CoC, the PI acknowledges that the study will need to be modified, the consent form will need to be changed, and the IRB may need to consider how already enrolled subjects are notified. | |
|  | | If the PI decides to extend or submit a new CoC, the PI acknowledges that they will submit a Report of New Information in Click and will work with the HRPP to prepare and submit the CoC application. | |
|  | | If a CoC is no longer in effect (e.g., NIH funding has ended, CoC expiration has not been extended), the CoC would not protect research subjects who begin their participation as research subjects after the CoC protection ended. | |