

Assurance Statement

Check the box next to the statement below if the statement is true:

- This request is submitted by an institutional official who has signature or other authority to submit this request.**
- 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. In addition, this institution will not utilize third parties or entities (e.g., contractors, online platform vendors) to collect or store information that cannot or will not protect against the compelled disclosure of the personally identifiable information.**
- The institution understands that research information protected by a Certificate of Confidentiality is subject to the protections and the disclosure requirements noted in 42 U.S.C 241. Any investigator or institution conducting research protected by a Certificate of Confidentiality 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 research without the specific consent of the individual to who the information pertains or as otherwise permitted in accordance with 42 U.S.C 241.**
- This Certificate of Confidentiality will not be represented as an endorsement of the project by the HHS or NIH or used to coerce individuals to participate in the research project.**
- The research will be conducted in accordance with 45 CFR 46 and relevant Subparts (even if not specifically required by regulation), as well as all applicable federal, state, and local laws and regulations throughout the life of the study. The Cooperative Research mandate at 45 CFR 46.114 is an exception. Single IRB will be used at institutional discretion.**

- All individuals from who informed consent will be obtained will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate and disclosures outside the scope of coverage of the Certificate (e.g., public health reporting as required by Federal, State, or local laws, or requirements for child or elder abuse reporting). Individuals who give informed consent and continue study participation after the expiration or termination of the Certificate will be informed that the protections of the Certificate may not cover any new data that is**

collected. Any individual from whom informed consent will be obtained 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.

Submit