


Attachment 1

OMB #0925-0689

OMB Expiry Date: 04/30/2025

Burden Disclosure: 

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 and 42 CFR § 2a**. 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 whom the information pertains or as otherwise permitted in accordance with **42 U.S.C 241 and 42 CFR § 2a**.
- 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 institution and personnel involved in the conduct of the research will comply with the informed consent requirements of the applicable Federal regulations, including 45 CFR Part 46.
- 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 and disclosures that are 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). 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.

Submit