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
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 whom 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 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