



10/18/2022

Stefan G Kertesz, MD, MSc
Birmingham Veterans Affairs Health Care System
700 19th Street South
Birmingham, AL, 35233

Dear Stefan G Kertesz, MD, MSc

Enclosed is the Confidentiality Certificate, protecting the identity of research participants in your project entitled, "Clinical Context of Suicide Following Opioid Transitions in Veterans (CSI:OPIOIDS-V)".

You and your institution's responsibilities related to this Certificate are outlined on the [NIH Certificate of Confidentiality website](#) and in the [Institutional Assurance Statement](#). You and your institution's responsibilities include that you cannot release a participant's identifiable, sensitive information to any other person not connected with the research OR in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.

Protections against disclosure under the Certificate of Confidentiality are limited in certain circumstances. Disclosure of information, physical documents, or biospecimens is not protected by the Certificate when this information or material is associated with mandatory reporting by Federal, State, or local laws, including reporting of child and elder abuse and specific infectious diseases.

Research participants must be informed about the Certificate protections under the applicable regulations at [Title 42 CFR Part 2a.4](#). In addition, participants must be informed about any exceptions to those protections, such as the mandatory reporting described above. Sample informed consent language can be found at <https://grants.nih.gov/policy/humansubjects/coc/helpful-resources/suggested-consent.htm> that may be used or adapted as appropriate.

If you make a significant change to the research project for this study (e.g., change of principal investigator or institution, change in the scope or direction of the research), you will need to obtain a new Certificate of Confidentiality to continue protections for new data collection. You may make a request through the [NIH online CoC system](#).

If legal action is brought to release personally identifying information protected by a Certificate of Confidentiality you should immediately seek legal counsel from your institution.

As a reminder, your institution has attested that the research activities will be conducted in accordance with all applicable Federal, State, and local laws and regulations.

Please contact the NIH Certificate of Confidentiality Coordinator if you have any questions about your Certificate of Confidentiality at NIH-CoC-Coordinator@mail.nih.gov.

Sincerely,

ANGELA Chambers
NIH Certificates of Confidentiality Coordinator
Office of Extramural Research
National Institutes of Health

Approval Date: 10/18/2022



CERTIFICATE OF CONFIDENTIALITY

Number:
CC-OD-22-3670

Issued To
Birmingham Veterans Affairs Health Care System

conducting research known as
Clinical Context of Suicide Following Opioid Transitions in Veterans (CSI:OPIOIDS-V)

In accordance with the provisions of section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d), this Certificate is issued to *Birmingham Veterans Affairs Health Care System* to protect the privacy of subjects in the above named research study, which is collecting or using identifiable, sensitive information. *Stefan G Kertesz* will serve as principal investigator. If there is a discrepancy between the terms used in this Certificate and section 301(d), the statutory language will control.

Research data and biospecimens containing identifiable, sensitive information collected or used during this study are covered by the Certificate beginning on the later of the approval date of this Certificate or the commencement of the project, until the collection or use of identifiable, sensitive information concludes. Identifiable, sensitive information protected by the Certificate and all copies thereof are protected for perpetuity.

The recipient of this Certificate shall comply with all requirements of subsection 301(d) of the Public Health Service Act. This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services.

10/18/2022

ANGELA Chambers

Approval Date

NIH Certificates of Confidentiality Coordinator
Office of Extramural Research
National Institutes of Health