DATE: XX, XX, XXXX

SUBJECT: Application for Certificate of Confidentiality Assurance Agreement

(Insert research study title)

On behalf of the University of Minnesota Office, this letter is provided to meet the Assurance Agreement requirements of the National Institute of Health Certificate of Confidentiality application submitted for the non-federally funded research project titled, (insert research study title).

The primary investigator for this project is (insert name and title), and the co-investigator is (insert name and title).

The agreement includes the following:

This institution agrees to use the Certificate of Confidentiality to protect against disclosure of personally identifiable information and to support and defend the authority of the Certificate.  Specifically, any investigator or institution conducting research protected by a Certificate of Confidentiality SHALL NOT, without the specific consent of the individual to who the information pertains:

* Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, 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 research; or
* 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.

Disclosure of protected information 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;
* Made with the consent of the individual to whom the information, document, or biospecimen pertain, including disclosure necessary for an individual’s medical treatment; or
* Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research

The institution understands that research information protected by a Certificate of Confidentiality and all copies thereof are protected in perpetuity and are subject to the protections and the disclosure requirements noted above.   
  
The institution understands that identifiable, sensitive information protected by the Certificate of Confidentiality and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be admissible as evidence or used for any purpose in any action, suite, or other judicial, legislative, or administrative proceeding.

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.  
  
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.

For studies in which informed consent is sought, subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate.

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.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Institutional Official Date

Chris Cramer, PhD

Vice President of Research