



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institute on Alcohol  
Abuse & Alcoholism  
5635 Fishers Lane  
Room 3111, MSC 9304  
Bethesda, MD 20892

8/26/2016

University of Wisconsin-Madison  
Dr. John Curtin  
327 Bascom Hall  
500 Lincoln Dr  
Madison, WI 53706

Dear Dr. Curtin,

Enclosed is the Confidentiality Certificate, protecting the identity of research subjects in your single-site/single-protocol project entitled *"Dynamic, Real-time Prediction of Alcohol Use Lapse Using mHealth Technologies"*.

Please note that the Certificate expires on 12/31/2022.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its limits and exceptions.

If you determine that the research project will not be completed by the expiration date, 12/31/2022, you must submit a written request for an extension of the Certificate three (3) months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reason for the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please advise me of any situation in which the certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to:

**Isabel Ellis M.S.W.**  
**National Institute on Alcohol Abuse & Alcoholism**  
**5635 Fishers Lane**  
**Room 3111, MSC 9304**  
**Bethesda, MD 20892**

Sincerely,

Approved Date: 08/26/2016

**Isabel Ellis M.S.W.**  
**Public Health Analyst**  
**National Institute on Alcohol Abuse & Alcoholism**

Enclosure



## CONFIDENTIALITY CERTIFICATE

CC-AA-16-043

issued to

*University of Wisconsin-Madison  
conducting research known as  
"Dynamic, Real-time Prediction of Alcohol Use Lapse Using mHealth Technologies"*

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 in response to the request of the Principal Investigator, Dr. John Curtin, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. John Curtin is primarily responsible for the conduct of this research, which is funded by:

Institution Center: NIAAA, Grant Number: 1R01AA024391-01

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1. are enrolled in, employed by, or associated with University of Wisconsin-Madison (UW) and its contractors or cooperating agencies, and
2. have in the course of their employment or association access to information that would identify individuals, who are the subjects of the research, pertaining to the project known as "Dynamic, Real-time Prediction of Alcohol Use Lapse Using mHealth Technologies"
3. are hereby authorized to protect the privacy of the individuals, who are the subjects of that research, by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

The purpose of this research project is to examine the use of an mHealth continuing care platform for addiction, A-CHESS (Alcohol Comprehensive Health Enhancement Support System), along with real-time measures of life stress, in identifying when subjects are at the greatest risk of relapse.

A Certificate of Confidentiality is needed because sensitive information will be collected during the course of the study. The certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological and social consequences.

All data will be coded by participant number only. The participant number and name will only be linked in the universities' secure OnCore servers. Consent forms with participant's name will be

stored in secure filing cabinets in locked rooms in the PI's laboratory in the UW Department of Psychology and separate from all participant data. Participant contact information and data from their initial phone screen interview will be stored securely on UW-Qualtrics and/or UW-ICTR OnCore servers which have accepted measures to protect participant confidentiality and are compliant with all national clinical research policies. All other data are collected and stored electronically on a secure server in the UW Department of Psychology, UW Qualtrics, and/or OnCore.

This research began on 06/01/2016, and is expected to end on 12/31/22.

As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This Certificate does not protect you from being compelled to make disclosures that: (1) have been consented to in writing by the research subject or the subject's legally authorized representative; (2) are required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or regulations issued under that Act; or (3) have been requested from a research project funded by NIH or DHHS by authorized representatives of those agencies for the purpose of audit or program review.

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire on 12/31/2022. The protection afforded by this Confidentiality Certificate is permanent with respect to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during the time the Certificate is in effect.

Sincerely,

8/31/2016  
Signed Date:

Patricia Powell  
Patricia Powell, Ph.D.  
Acting Deputy Director  
National Institute on Alcohol Abuse & Alcoholism