



National Institutes of Health
National Institute of
General Medical Sciences
Bethesda, Maryland 20892-6200
<http://www.nigms.nih.gov>

February 27, 2020

TO: Office of Management and Budget (OMB)
Through: Debbie Kramer, Reports Clearance Officer, DHHS _____
Mikia Currie, Project Clearance Chief, NIH _____

FROM: Dr. Pamela Kearney, Director, Division of Human Subjects Research
Office of Extramural Research (OER)

SUBJECT: Non-substantial Change Request to Electronic Application for NIH
Certificates of Confidentiality (CoC E-application System) (OMB# 0925-
0689) ; Expiration Date: 02/28/2023)

We are writing to request approval of some non-substantial changes to data collection instruments scheduled for use as part of the Electronic Application for NIH Certificates of Confidentiality (CoC E-application System) (OMB# 0925-0689). The proposed modifications are wording changes to add clarity for respondents. They do not change the scope of the inquiry; the method of collection or the population of participants outlined in the original application, or the estimated burden of the collection.

For clarification purposes, we have modified the wording of the two questions below: 1) Question 6, to further specify what is meant by the term "modification of informed consent" and to be consistent with regulatory language; and 2) the last item in Question 1.6.1., to clarify language about disclosures outside the scope of coverage of the Certificate; and expand on and clarify the examples of such disclosures. Proposed wording changes are highlighted in **YELLOW** below. No questions have been added or removed to the data collection instrument.

Original Question	Proposed Change
<p>6. Is a modification of informed consent under 45 CFR 46 to be used?</p> <p>If yes, has the modification been approved by the IRB in accordance with 45 CFR 46?</p>	<p>6. Is a waiver or alteration of informed consent under 45 CFR 46 to be used?</p> <p>If yes, has the waiver or alteration been approved by the IRB in accordance with 45 CFR 46?</p>

1.6.1. 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 outside the scope of coverage of the Certificate (e.g. **infectious disease, child or elder abuse** reporting as required by Federal, State, or local laws). 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.

1.6.1. 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.

Pamela R. Kearney, M.D.



Attachments:

Screenshots of Proposed Electronic Application for NIH Certificates of Confidentiality (CoC E-application System)