NIH/OD/OER/OEP HUMAN SUBJECTS:
KIOSK Updated Mockup Screens

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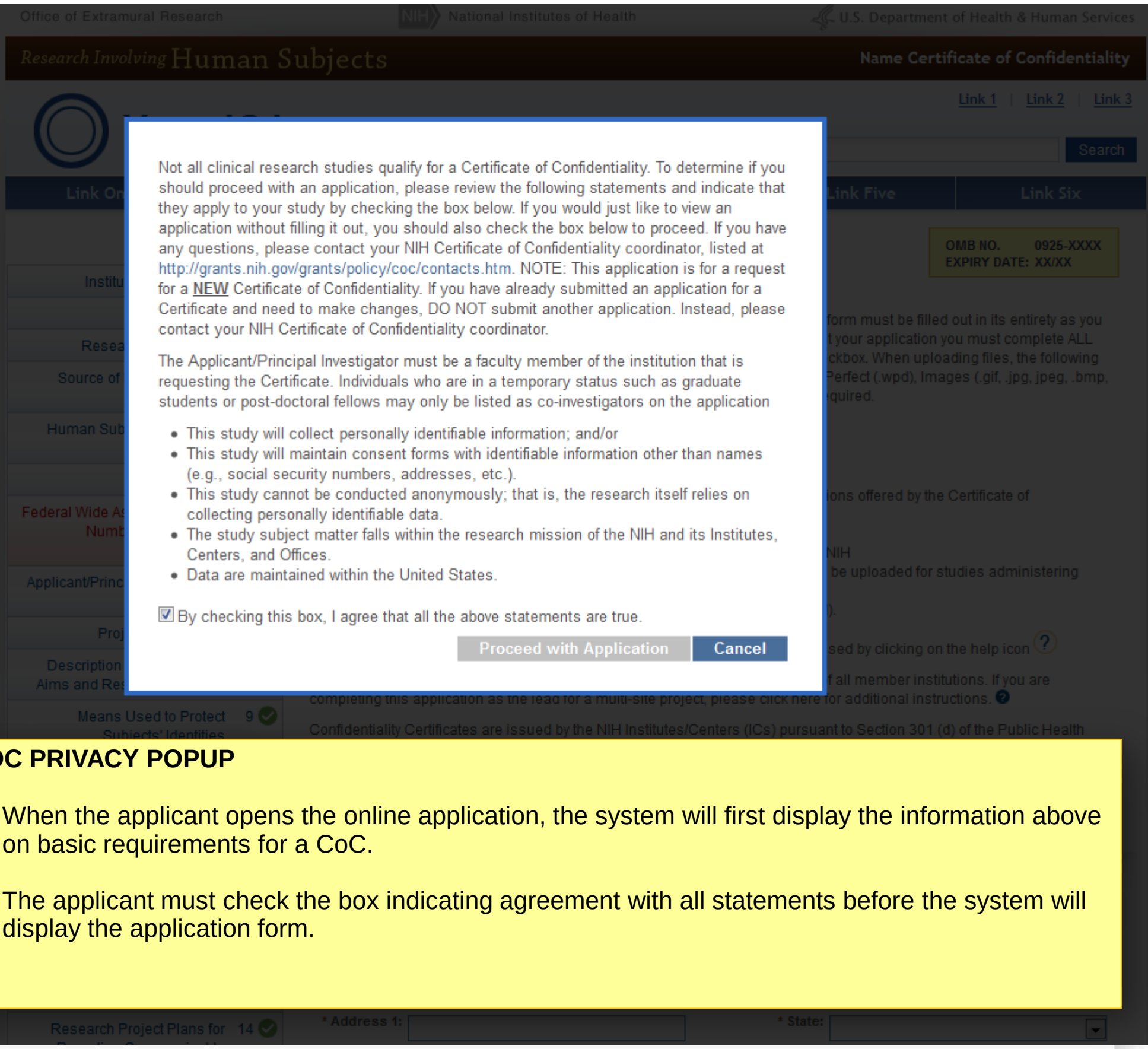
Sydney Gomes

Aug, 2013

NETE = NET EFFECT
INTEGRATED MANAGEMENT COSULTING l ENTERPRISE ARCHITECTURE l TECHNOLOGY SOLUTIONS l WEB l INTERACTIVE

APPLICANT SECTION WIREFRAMES

CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION



COC PRIVACY POPUP

- When the applicant opens the online application, the system will first display the information above on basic requirements for a CoC.
- The applicant must check the box indicating agreement with all statements before the system will display the application form.

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FEDERAL HEALTH | IT

Office of Extramural Research | NIH National Institutes of Health | U.S. Department of Health & Human Services

Research Involving Human Subjects — Name Certificate of Confidentiality

Your IC Logo

Link 1 | Link 2 | Link 3

Search

Link One | Link Two | Link Three | Link Four | Link Five | Link Six

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- IRB Approval 5(b)
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Application for NICHD Certificate of Confidentiality

OMB NO. 0925-XXXX
EXPIRATION DATE: XX/XX

Welcome to the Application for Certificate of Confidentiality. To successfully submit your application you must complete ALL sections below. If a section does not apply to you, select the "Not Applicable" checkbox. When uploading files, the following types are allowed: Microsoft Word (.doc, .docx), Microsoft Excel (.xls, .xlsx), Word Perfect (.wpd), Images (.gif, .jpg, jpeg, .bmp, .tiff, and .tif), and Adobe Acrobat (.pdf). All fields marked with an asterisk (*) are required.

To complete this application, you will need:

- Your institution's Federalwide Assurance number (FWA)
- Documentation of IRB approval (to be uploaded)
- The IRB-approved consent form with appropriate language about the protections offered by the Certificate of Confidentiality (to be uploaded)
- A brief description of the research study
- Information about drugs to be administered (only for research projects not funded by NIH)
- A copy of the Drug Enforcement Administration Certificate of Registration (to be uploaded for studies administering controlled drugs)
- A signed copy of the required assurance form (to be scanned and uploaded).

Additional information is available for many of the items below and can be accessed by clicking on the help icon

For multi-site projects, a lead institution should apply for a Certificate on behalf of all member institutions. If you are completing this application as the lead for a multi-site project, please click here for additional instructions.

Confidentiality Certificates are issued by the NIH Institutes/Centers (ICs) pursuant to Section 301 (d) of the Public Health Service U.S.C. Section 241 (d) to afford special privacy protection to subjects enrolled in biomedical, behavioral, clinical, or other research within NIH mission areas. A Certificate helps the researcher avoid compelled 'involuntary disclosure' (e.g. subpoenas) of identifying information about a research subject. For additional general information on Certificates of Confidentiality, including sample consent language, please visit the NIH Certificate of Confidentiality Kiosk at http://grants.nih.gov/grants/policy/coc/.

Public reporting burden for this collection of information is estimated to average 90 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-XXX). Do not return the completed form to this address.

1 INSTITUTION INFORMATION

This is the institution with which the applicant (principal investigator) is affiliated and the recipient of funding for the research, if there is any. The principal investigator must be a faculty member of this institution. Individuals who are in a temporary status such as graduate students or post-doctoral fellows may only be listed as co-investigators in this application.

* Institution Name:		* City:	
* Address 1:		* State:	
Address 2:		* Postal Code:	
Address 3:		* Country:	
Address 4:		* Institutional Official:	
Address 5:		* Organizational Title:	

2 RESEARCH SITES

List the primary site where the research will be conducted and a brief description of the facilities available for the conduct of the research. The lead site of a multi-site project should apply for a single Certificate to protect participants enrolled at all sites and should maintain a current listing of other sites.

* Primary Site
You have 300 characters remaining

* Brief Description of Facilities:
You have 600 characters remaining

KIOSK COC FORM – STYLE 2
TABBED VIEW

- The design concept includes the left panel to navigate within sections of the form.
- The navigation panel will be highlighted to showcase the parts of the form that have been completed (with a green check) and those parts that still need to be completed (in red).
- Design will hold all the template feature of customizing it to the IC branding

4 SOURCE OF PROJECT FUNDING SUPPORT

Is the research funded by NIH

YES

Please list the funding Institute/Center (IC):

CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (1 TO 2)

Application for NICHD Certificate of Confidentiality

OMB NO. 0925-XXXX
EXPIRATION DATE: XX/XX

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* Institution Name:
* Address 1:
Address 2:
Address 3:
Address 4:
Address 5:
* City:
* State:
* Postal Code:
* Country:
* Institutional Official:
* Organizational Title:

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* Primary Site

You have 300 characters remaining

* Brief Description of Facilities:

You have 600 characters remaining

CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (3 TO 5C)

3 RESEARCH PROJECT TITLE

Please enter the title of the research project in the box below. If the project title on the IRB form (see item 5 below) is different from title given here, the applicant must document that the IRB approval pertains to this project.

Include all alternate titles in addition to the IRB approved title. Alternate titles may be listed on the consent form, award letters, collaborative agreements, clinical trials registry listing, etc. When entering the titles below, put "also known as" between them.

* **Title(s):**

4 SOURCE OF PROJECT FUNDING SUPPORT

Is the research funded by NIH

- (•) YES
  - Please list the funding Institute/Center (IC): (for example NIDA)
  - Grant Number: (for example 1R01CA123456-01)
- ( ) NO

Please indicate the primary funding source

- [ ] Internal Institutional funding
- [ ] Other DHHS agency (Specify; 50 characters maximum)
- [ ] Other Federal agency (Specify; 50 characters maximum)
- [ ] State or local government funding
- [ ] Foundation or non-profit organization (Specify; 50 characters maximum)
- [ ] Other Source (Specify; 100 characters maximum)
- [ ] None

5.a HUMAN SUBJECTS PROTECTION REQUIREMENTS

A Certificate of Confidentiality will not be issued to an applicant unless the project has IRB approval. The approving IRB must be in compliance with applicable Federal requirements. If the applicant institution is receiving DHHS funding for research involving human subjects, an OHRP-approved IRB for that institution must approve the project for which a Certificate of Confidentiality is sought. For additional information on OHRP and IRB assurances, see http://www.hhs.gov/ohrp/assurances/

If the applicant institution has not received DHHS funding for this research but has an IRB that complies with the requirements for IRBs imposed by another Federal agency, that IRB must approve the research. If the applicant institution does not have an IRB, the project should be reviewed by an IRB in accordance with 45 CFR Part 46.

5.b IRB APPROVAL

Attach letter or form signed by an authorized IRB representative. Approval must be current and unconditional, or conditioned only upon the issuance of a Certificate of Confidentiality. If this is a multi-site project, only the lead site IRB approval needs to be submitted, but the lead site must maintain copies of the IRB approval from each site, to be made available to the NIH upon request.

* **Name Of IRB:**

* **Letter Of Approval:** Browse

CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (5C - 6)

5.c FEDERALWIDE ASSURANCE (FWA) NUMBER/STATEMENT OF QUALIFICATIONS

Submit for the IRB that reviewed the project, the federalwide assurance (FWA) number assigned by OHRP or a statement of qualifications that the IRB complies with the applicable Federal regulations governing research involving human subjects. If this is a multi-site project, only the FWA from the lead site IRB is required.

* FWA Number:

OR

You have 300 characters remaining

* Statement Of Qualifications:

6 APPLICANT/PRINCIPAL INVESTIGATOR INFORMATION

Please provide the work information for the applicant/principal investigator (PI) as well as name and title of other key personnel. Also include a brief summary of the scientific training of the PI and key personnel. If this is a multi-site project, only information for PI of the lead site should be submitted to the NIH. However, the lead site must collect and maintain this information from each site. Also, you may add an email address for an alternate contact person for this application (such as the PI's administrative assistant or research coordinator).

If there are multiple co-investigators, they can be added using the "Enter More Key Personnel" button. If any of these additional investigators are co-principal investigators, this should be noted in the summary of scientific training box. Alternatively, a listing of key personnel can be uploaded and the additional co-principal investigators can be noted in that document.

Briefly, in no more than 2 or 3 sentences, state the qualifications of the Principal Investigator and note the PI's faculty affiliation with the submitting institution.

Example of Summary of Scientific Training
- *PhD received from Green University in Clinical Psychology in 1978*
- *Academic Faculty full time at Orange University from 1981 until present*

Copy Institution Address

* Applicant Title:
* First Name:
* Last Name:
* Organizational Title:
* Address 1:
Address 2:
Address 3:
Address 4:
Address 5:

* City:
* State:
* Postal Code:
* Country:
* Telephone:
* Fax:
* Email:
* Confirm Email:
* Alternate Email:
* Confirm Email:

You have 300 characters remaining

* Summary Of Scientific Training:

Key Personnel

If you have more than one key person to add, either add them individually by selecting the Enter More Key Personnel button or by uploading a document containing a list of the key personnel by selecting the Browse button. If you intend to add more than 20 key personnel, you must upload a document.

Upload Document Containing All Key Personnel: Browse

OR

Name:

Title:

You have 300 characters remaining

Summary Of Scientific Training:

Enter More Key Personnel

CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (7 TO 9)

7 PROJECT DATE RANGE

Please enter the date the project began or will begin and the date the project is expected to end; these will be used to set the start and expiration dates on your Certificate. If the research will not be completed by the expected end date, the Applicant must contact the NIH Certificate Coordinator about extending the protection; this should be done three months prior to the end date.

* Beginning Date (mm/dd/yyyy):

* End Date (mm/dd/yyyy):

8 DESCRIPTION OF STUDY PROJECT AIMS AND RESEARCH METHODS

This section should include a description of the project as well as a 2 or 3 sentence brief summary of the project which will be included in the Certificate. If significant changes are made to the project aims or methods after a Certificate has been issued the Applicant should contact the NIH Certificate Coordinator to determine if the Certificate can be modified or if the Applicant will need to submit an amendment application.

Example of Description of Study:
The proposed study will investigate the occurrence of maternal depression, parenting attitudes and social support, and the effects of these on infant developmental risk in a group of rural, Native American mothers. The study also examines the detrimental effects of poverty and environmental deprivation on children as mediated through mothers' psychological and social well-being and parenting behavior in the early years. In addition, the proposed study would determine prevalence rates of infant cognitive and developmental delay at one year as a developmental outcome measure. Finally the study will look at social support as a powerful moderator of maternal psychological functioning, and a buffer to risk for children.

The study has four main objectives

1. To determine the relatedness of maternal depressive symptoms to maternal prenatal risk behaviors, ie., smoking, alcohol and drug abuse during pregnancy.
2. To determine the occurrence and relatedness of maternal depressive symptoms and poor parenting attitudes at infant age 2 days, 2 months, and at 1 year in this population.
3. To discover maternal perceptions of social support (extended family and partner),and test the hypothesis that social support alleviates maternal depressive symptoms and poor parenting attitudes.
4. To test the hypothesis that infant developmental delay at 1 year is related to maternal depressive symptoms and attitudes, moderated by social support.

Example of Brief Summary:
This behavioral research study examines the relationship between maternal depressive symptoms, pre-natal risk behavior, perceived social support, and infant outcomes. Approximately 200 Native American mother-infant pairs will be recruited as subjects and evaluated at baseline and scheduled intervals for one year.

* Description of Study - You have 3000 characters remaining

* Brief Summary - You have 1000 characters remaining

9 MEANS USED TO PROTECT SUBJECTS' IDENTITIES

Describe the procedures used for collection and storage of personally identifiable information.

For Example: *Subjects are coded by numbers not names, linking information is kept in locked files, identifiers will be destroyed when the study is completed, etc.*

* Means Used - You have 3000 characters remaining

CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (10 TO 12)

10 REASONS FOR REQUESTING A CERTIFICATE OF CONFIDENTIALITY

Include a brief description of sensitive and identifying information to be collected.

Examples for Reason for Requesting Certificate of Confidentiality:

- *Sensitive information regarding drug and alcohol use, physical habits and dream content are being collected.*
- *Genetic material is being collected in patients and their families who may be at risk of developing specified diseases.*
- *Genome analysis will be performed to search for familial, disease-influencing genes and their alleles.*

This information, if disclosed, could expose subjects or their families to adverse economic, legal, psychological or social consequences

*** Reason for Request – You have 1000 characters remaining.**

11 INFORMED CONSENT FORM(S) FOR HUMAN SUBJECTS, AS IT WILL READ IF THE CERTIFICATE OF CONFIDENTIALITY IS ISSUED (ATTACH COPY)

The informed consent form must include an accurate description of the protections and limitations of the Certificate of Confidentiality, including the circumstances in which the investigators plan to voluntarily disclose identifying information about research participants (e.g., child abuse, harm to self or others, etc.). **Sample language can be viewed here**

Researchers may adapt the sample language to the fit the needs of the research participants and to the subject matter of the study. However, the language used must cover the basic points about the Certificate and its protections. Researchers should ensure that the language about confidentiality and data security included in the consent forms is consistent with the protections of the Certificate of Confidentiality.

The researchers must also include language regarding circumstances that could lead to voluntary disclosure to authorities and appropriate professionals, without consent of the participant, such as information about child abuse, intent to hurt self or others, or other disclosures (including a description of the circumstances under which disclosures would be made).

If this is a multi-site project, only submit the consent form used by the lead site. The lead site must maintain copies of the IRB-approved consent form(s) from each participating site and must ensure that informed consent form for each site contains appropriate language about the protections and limitations (voluntary disclosures) of the Certificate of Confidentiality.

If a study uses several consent forms (e.g. a consent form and an assent form), please merge them into a single document prior to uploading.

If significant changes are made to the informed consent form after the Certificate has been issued, the Applicant should contact the Certificate Coordinator to determine if a revised consent form should be submitted to NIH.

Information for research projects with children: A Certificate of Confidentiality cannot be used to refuse to disclose identifiable research information about a minor if a parent or legal guardian requests it. The researchers may use other basis for a refusal to disclose information - after checking with their IRB about waivers of parental permission and other issues. In any case, researchers should discuss this possibility with their institution's officials.

Researchers may contact the Certificate Coordinator at the NIH IC for which they are applying with questions or additional recommendations and suggestions on language to be included in consent and assent forms regarding the Certificate of Confidentiality. (IC Contacts)

*** Informed Consent Form(s):** Browse

12 ADMINISTRATION OF DRUGS IN RESEARCH NOT FUNDED BY NIH

Research not funded by NIH in which drugs will be administered to human subjects must provide the following additional information:

- Identification of drugs to be administered; e.g. Phenobarbital
- Description of methods for administration of these drugs, including a statement of dosages; e.g. 50 to 100 mg 2 to 3 times daily.
- Evidence that individuals who will receive the drugs are authorized to do so under applicable Federal and State law. e.g. Patients with Alzheimer's are allowed to use anti-epileptic medications in the State of Rhode Island.

If you have more than one drug to be administered, add each one individually by selecting the Enter More Drugs button (limit 20 drugs).

Select this checkbox if this section is not applicable (n/a) to your application:

* Identification Of Drug	* Description Of Administration Of Drug	* Evidence Of Authorization
You have 300 characters remaining	You have 300 characters remaining	You have 300 characters remaining

Enter More Drugs

CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (13 TO 15)

13 ALL RESEARCH IN WHICH A CONTROLLED DRUG OR DRUGS WILL BE ADMINISTERED (ATTACH COPY)

All research in which a controlled drug or drugs will be administered must upload a copy of the Drug Enforcement Administration Certificate of Registration (BND Form 223) under which the research project will be conducted.

Select this checkbox if this section is not applicable (n/a) to your application:

* Upload Scanned Copy Of The DEA Form:

Browse

14 RESEARCH PROJECT PLANS FOR REPORTING COMMUNICABLE DISEASES

If the research project is testing for reportable communicable diseases, the applicant must submit information relating to its plans for working with State and local authorities as specified in the August 9, 1991 memorandum from the Assistant Secretary for Health (http://grants.nih.gov/grants/policy/coc/cd_policy.htm).

Select this checkbox if this section is not applicable (n/a) to your application:

* Plans for Reporting Communicable Diseases - You have 1000 characters remaining

15 ASSURANCES

Please provide a scanned copy, on institutional letterhead, of the assurances referencing this application with signatures, identification of the signatories, and the date of the signing. Both the PI and the Institutional Official named in this application must sign this letter. If you are a lead site applying for a Certificate for a multi-site project, please upload the assurance from your institution. The lead site is also responsible for obtaining similar signed assurances from all of the participating institutions and should develop appropriate agreements with these institutions to implement the assurances.

The following assurances are required and should be inserted verbatim into the assurance letter to be signed and uploaded into this application:

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.

The institution and personnel involved in the conduct of the research will comply with the applicable Federal regulation for the protection of human subjects or, if no such Federal regulation is otherwise applicable, they will comply with 45 CFR Part 46.

This Certificate of Confidentiality will not be represented as an endorsement of the project by the DHHS or NIH or used to coerce individuals to participate in the research project.

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.

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.

* Upload scanned signed assurance form

Browse

Save Draft Submit to NIH

THANK YOU.

Presentation Created by:
RK Allam, allamr@mail.nih.gov
Syd Gomes, gomessa@mail.nih.gov