

NCI OCR Attachment 10

NCI OCR Electronic Investigator Registration – Protocol and Annual

Step 1: User accesses the NCI Online Credentialing Repository (OCR) at <http://ocr.nci.nih.gov> – see screenshot, page 2

Step 2: User enters “Username” and “Password” and clicks “Login” - see screenshot, page 2

Step 4: User reviews NCI OCR privacy– see screenshot, page 3

Step 5: System displays “Investigator Task List” page – see screenshot, page 4

Step 6: Alternative workflows, a OR b, a user may perform any of these actions upon entering the system:

- a. User selects to complete “Protocol Registration” for DCP and completes 1572, FDF, and CV – see screenshots, pages 5 - 11, OR
- b. User selects to complete “Annual Registration” for CTEP and completes 1572, FDF, IDF, and CV – see screenshots, pages 12 – 19, OR

Step 8: User signs registration package and submits to NCI – see screenshot, page 20,

OCR - Online Credentialing Repository

**OCR
Home**

[? Help](#)

New users, click on the "Request a new account" link to register for an NCI OCR user account. Returning users, please enter your NIH/NCI credentials to log into NCI OCR. You can email NCICB Application Support at ncicb@pop.nci.nih.gov if you have questions or need assistance.

Username

Password

Identity Provider
Dorian

[Request a new account](#)

Version: 3.2

OCR Privacy

OCR - Online Credentialing Repository

Sign Out

Help

****WARNING****

You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties.

By using this information system, you understand and consent to the following:

1. You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system.
2. Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

PRIVACY ACT NOTIFICATION STATEMENT FOR NCI OCR

The web portal for the NCI OCR (Online Credentialing Repository) asks investigators to submit personal information. The primary use of this application is as an online mechanism for submitting the FDA Form 1572 for investigator registration to the National Cancer Institute. NCI OCR stores your information securely between submissions (i.e., subsequently you will only need to update what changed since your submission), and allows you (appropriately authorized users) to apply a digital signature to the completed form. Collection of this information is authorized under Section 405 of the Public Health Service Act, 42 U.S.C. 284(b)(1) and Privacy Act System Notice D9-25-D200 (<http://oma.od.nih.gov/ms/privacy/pa-files/D200.htm>). This information may be disclosed to researchers for research purposes, contractors responsible for the maintenance of the repository and to other registered repository users for non-commercial, scientific and educational purposes. Submission of this information is voluntary, but it is required for registration with the National Cancer Institute to conduct a clinical trial.

The NCI OCR web portal also records IP addresses and aggregated user query information. However, the IP address is not associated with any user registration information. The user registration data, IP addresses and aggregated user query information are used for NCI internal reporting purposes only to allow for improvement of the NCI OCR web portal based on users needs. For additional information, please refer to the link to our Privacy Policy <http://www.nih.gov/about/privacy.htm>

I have read this Privacy Act Notification Statement.

Accept

Reject

Version: 3.2

OCR - Online Credentialing Repository

Home Investigator ▾ Welcome **Tanya Shedrick** ▾ Sign Out

Home

Welcome to the NCI Online Credentialing Repository! [? Help](#)

Task List

Search:

Description	Date
Answer invitation to register for Protocol 123456789.	12/27/2012
Answer invitation to register for Protocol 234567890.	12/27/2012
Resume your investigator registration for Protocol 012345678.	12/27/2012

Version: 3.2

**Initial Landing
Page/Task List**

Home Investigator ▾ Welcome **Tanya Shedrick** ▾ Sign Out

Registration for Tanya Shedrick to 012345678 Sample Protocol 3 Help

Protocol Info Summary Subinvestigators 1572 Financial Disclosure CV Human Research Certificate Additional Attachments

Status: In Progress

Registration Forms

[Submit for Review](#)

Form	Optionality	Status Date	Status
Curriculum Vitae	Required	12/27/2012 4:26 PM	Not Started
FDA Form 1572: Statement of Investigator	Required	12/27/2012 4:30 PM	In Progress
Financial Disclosure Form	Required	12/27/2012 4:26 PM	Not Started
Protection of Human Research Subjects Training Certificate	Required	12/27/2012 4:26 PM	Not Started
Additional Attachments	Supplementary		Not Applicable

Version: 3.2

**DCP
Protocol
Registration**

DCP Protocol 1572 Form

Home Investigator Welcome **Tanya Shedrick** [Sign Out](#)

Registration for Tanya Shedrick to 012345678 Sample Protocol 3 [? Help](#)

Protocol Info | Summary | Subinvestigators | **1572** | Financial Disclosure | CV | Human Research Certificate | Additional Attachments

FDA 1572 OMB#: 0925-0613 EXP. DATE: XX/XX/2016

[View Generated 1572](#)

Public reporting for this collection of information is estimated to average 15 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. 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 (0925-0613). Do not return the completed form to this address.

Identify the practice sites where the clinical investigation will be conducted, clinical laboratory facilities that will be used in the study, and IRBs that are responsible for review and approval of the study by turning on the checkboxes next to the appropriate organizations. Your selections will be saved automatically and appear on your Form FDA 1572.

Practice Sites [Add Practice Site...](#)

Name	CTEP ID	OHRP Assurance #	Address	Phone Number
No data available in table				

Clinical Laboratories [Add Clinical Lab...](#)

Name	Address	Phone Number
No data available in table		

Institutional Review Board [Add IRB...](#)

Name	Address	Phone Number
No data available in table		

[View Generated 1572](#)

Version: 3.2

Registration for Tanya Shedrick to 012345678 Sample Protocol 3



- Protocol Info
- Summary
- Subinvestigators
- 1572
- Financial Disclosure
- CV
- Human Research Certificate
- Additional Attachments

National Cancer Institute, Division of Cancer Prevention (NCI DCP) FINANCIAL DISCLOSURE FORM

OMB#: 0925-0613 EXP. DATE: XX/XX/2016

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Public reporting for this collection of information is estimated to average 5 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. 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 (0925-0613). Do not return the completed form to this address.

Indicate by marking YES or NO if any of the financial interests or arrangements as described below apply to you, your spouse, or dependent children cumulatively. If the information changes during the course of the study or within one year after completion of the study, please notify NCI, DCP. Your responses will be saved automatically.

Yes No Any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study (For example, compensation that is explicitly greater for a favorable outcome, or compensation to the investigator in the form of an equity interest in the sponsor or in the form of compensation tied to sales of the product, such as a royalty interest.) If yes, please attach details on a separate sheet.

Yes No Any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, excluding the costs of conducting this or any other clinical studies. This could include payments made to the investigator or institution to support activities that have a cumulative monetary value greater than \$25,000 (i.e., a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria). If yes, please attach details on a separate sheet.

**DCP
Protocol
Financial
Disclosure
Form**

Yes No Any proprietary or financial interest in the product tested in the covered study such as a patent, trademark, copyright, or licensing agreement. If yes, please attach details on a separate sheet.

Yes No Any significant equity interest in the sponsor, defined in 21 CFR 54.2(b), as any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices (generally, interests in a nonpublicly traded corporation), or any equity interest in a publicly traded corporation that exceeds \$50,000 during the time the clinical investigator is carrying out the study and for one year following completion of the study.

OR

I hereby certify that none of the financial interests or arrangements listed above exist for myself, my spouse, or my dependent children.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

Submission of attachments containing personal identity information (PII) is voluntary and is not required for registration with the National Cancer Institute (NCI) to conduct a clinical trial. If you choose to attach a file containing PII, you are doing so voluntarily and the personal information contained in the file will not be disclosed.

File:

Name	Upload Date	Download
No data available in table		

[View Generated Financial Disclosure PDF](#)

Version: 3.2

Home Investigator v Welcome Tanya Shedrick v Sign Out

Registration for Tanya Shedrick to 012345678 Sample Protocol 3 Help

Protocol Info Summary Subinvestigators 1572 Financial Disclosure CV Human Research Certificate Additional Attachments

Protection of Human Research Subjects Training Certificates

You must select at least one Protection of Human Research Subjects training certificate. You may add certificates by pressing the button below.

Add Training Certificate

File Name	Organization Name	Effective Date	Expiration Date
<input checked="" type="checkbox"/> CLIA_CERT_T.gif	National Institutes of Health - Office of Extramural Research	11/1994	11/2012

Version: 3.2

DCP Protocol PHRS Training Certificate

Home Investigator v Welcome Tanya Shedrick v Sign Out

Registration for Tanya Shedrick to 012345678 Sample Protocol 3 Help

Protocol Info Summary Subinvestigators 1572 Financial Disclosure CV Human Research Certificate **Additional Attachments**

Additional Attachments

Identify which file(s) you would like to include with the submission of your protocol registration by selecting the checkbox next to the file(s). Your selections will be saved automatically and the files will be included with your submission. You can also upload new files. Submission of attachments containing personal identity information (PII) is voluntary and is not required for registration with the National Cancer Institute (NCI) to conduct a clinical trial. If you choose to attach a file containing PII, you are doing so voluntarily and the personal information contained in the file will not be disclosed.

[Add New](#)

File Name	Description	Upload Date
<input checked="" type="checkbox"/> Sample File.pdf	Supplemental Information	12/28/2012

Version: 3.2

**DCP Protocol
Additional
Attachments**

OCR - Online Credentialing Repository

Home Investigator ▾ Welcome **Eric Tavela** ▾ Sign Out

Browse Annual Registrations Help

Food and Drug Administration (FDA) regulations and NCI policy require all investigators participating in any NCI-sponsored clinical trial to register and to renew their registration annually. You are only required to register if you wish to participate in NCI-sponsored clinical trials. If you were invited to register for a protocol study, use the Protocol Registrations menu item.

Type	Status	Submission Date	Due Date	
Initial	● Not Started	N/A	N/A	Edit

Form	Optionality	Last Update	Status
FDA Form 1572: Statement of Investigator	Required	08/22/2012	Not Started
Financial Disclosure Form	Required	08/22/2012	Not Started
Supplemental Investigator Data Form	Required	08/22/2012	Not Started
Additional Attachments	Supplementary	08/22/2012	Not Applicable




**Browse CTEP
Annual
Registrations**

Summary | 1572 | Financial Disclosure | Supplemental Investigator Data Form | Additional Attachments


Status: In Progress (0/3 required forms complete)

Submit for Review

Required Forms

 <p>FDA Form 1572: Statement of Investigator In Progress Last Updated: 12/27/2012</p>	 <p>Financial Disclosure Form Not Started Last Updated: 12/27/2012</p>
 <p>Supplemental Investigator Data Form Not Started Last Updated: 12/27/2012</p>	

Supplemental Forms

 <p>Additional Attachments Not Applicable Last Updated: 12/27/2012</p>

CTEP Annual Registration Summary

CTEP Annual 1572 Form

FDA 1572

OMB#: 0925-0613 EXP. DATE: XX/XX/2016

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Identify the practice sites where the clinical investigation will be conducted, clinical laboratory facilities that will be used in the study, and IRBs that are responsible for review and approval of the study by turning on the checkboxes next to the appropriate organizations. Also, select one or both of the appropriate phase checkboxes for the NCI-sponsored clinical trials. Your selections will be saved automatically and appear on your Form FDA 1572.

Practice Sites

[Add Practice Site...](#)

Name	CTEP ID	OHRP Assurance #	Address	Phone Number
No data available in table				

Clinical Laboratories

[Add Clinical Lab...](#)

Name	Address	Phone Number
No data available in table		

Institutional Review Board

[Add IRB...](#)

Name	Address	Phone Number
No data available in table		

Phase Selection



For phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.



For phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as the controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

[View Generated 1572](#)

[Next \(Financial Disclosure\)](#)

CTEP Annual Financial Disclosure Form

National Cancer Institute, Division of Cancer Prevention (NCI, DCP) FINANCIAL DISCLOSURE FORM

OMB#: 0925-0613 EXP. DATE: XX/XX/2016

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The FDA requires that the following confidential financial disclosure information be collected for all investigators (see 21CFR 54.4). Any pharmaceutical company that submits a marketing application for any drug, biologic product, or device is required to submit certain information concerning the compensation to, and financial interests of, any clinical investigator participating in any clinical study submitted in the marketing application. The Cancer Therapy Evaluation Program (CTEP) is collecting this confidential information annually for all NCI-registered investigators.

Please indicate below if you, your spouse, or dependent children have any of the following disclosable financial arrangements.

- Yes No Do you currently have or have you at any time in the past year had any compensation made to you by a pharmaceutical company in which the value of the compensation could be affected by the study outcome?
- Yes No Do you currently have or have you at any time in the past year had a proprietary interest in any drug, biologic product, or device, including, but not limited to, a patent, trademark, copyright, or licensing agreement?
- Yes No Do you currently have or have you at any time in the past year had any equity interest in a pharmaceutical company that exceeds \$50,000 in value?
- Yes No Do you currently have or have you at any time in the past year had significant payments of other sorts totaling \$25,000 or more from any single pharmaceutical company to you or to your institution to support activities exclusive of the costs of conducting clinical studies, such as a grant to fund your ongoing research, compensation in the form of any equipment not directly related to the conduct of the clinical trial, or retainers to you for ongoing consultation or honoraria?

If you answered "Yes" to any of the questions above, please provide the name of the pharmaceutical company or companies with whom the financial arrangement exists (add an attachment if needed).

Pharmaceutical Companies

 Add Pharmaceutical Company...

Name	CTEP ID	Email	Phone Number	Address
No data available in table				

Showing 0 to 0 of 0 entries

Submission of attachments containing personal identity information (PII) is voluntary and is not required for registration with the National Cancer Institute (NCI) to conduct a clinical trial. If you choose to attach a file containing PII, you are doing so voluntarily and the personal information contained in the file will not be disclosed.

File:

Name	Upload Date	Download
No data available in table		

Completed forms will be maintained by the Pharmaceutical Management Branch, CTEP as part of your confidential investigator registration file. This information will only be provided (1) to a pharmaceutical company which has an agreement (e.g., a Clinical Trials Agreement [CTA] or a Cooperative Research and Development Agreement [CRADA]) with CTEP if CTEP is notified that a licensing application is being prepared by that company or (2) to a Cooperative Group of which you are a member if CTEP is notified that a clinical trial is being developed by that Group and a pharmaceutical company with whom you have indicated a financial arrangement. You may be contacted in the future by a pharmaceutical company representative or by your Cooperative Group administrative staff for additional information.

[View Generated Financial Disclosure PDF](#)

[Next \(Supplemental Investigator Data Form\)](#)

Summary 1572 Financial Disclosure **Supplemental Investigator Data Form** Additional Attachments

OMB#: 0925-0613 EXP. DATE: XX/XX/2016

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Supplemental Investigator Data Form

[View Generated Supplemental Investigator Data Form](#)

Professional Contact Information [Modify Contact Information](#)

1. Investigator Name	3. Email
2. Primary Address	4. Phone Number
	5. Provider No. (NPI)
	6. NCI Investigator Number

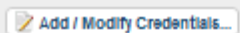
Primary Organization [Edit](#)

7. Name National Cancer Research Institute	9. CTEP ID
8. Address UNKNOWN UNKNOWN , UM 96960 USA	9. Email unknown@pdqload.org
	10. Phone Number

Credentials [Add / Modify Credentials...](#)

**CTEP
Supplemental
Investigator Data
Form**

Credentials



12. Work History

Position	Where	Start Date	End Date
No data available in table			

13. Professional Licenses

License Type	License Number/ID	Licensed in State/Province/Country	License Expiration Date
No data available in table			

14. Degrees

Degree	Institution	Date
No data available in table		

15. Internships

Certifying Board	Specialty	Where	Start Date	End Date
No data available in table				

16. Residencies

Specialty	Where	Start Date	End Date
No data available in table			

17. Fellowships

Sub-specialty	Where	Start Date	End Date
No data available in table			

18. Board Specialties

Board	Specialty	Eligible/Certified	Effective Date	Expiration Date
No data available in table				

19. Protection of Human Research Participants

Organization Name	Effective Date	Expiration Date
No data available in table		

[View Generated Supplemental Investigator Data Form PDF](#)

[Next \(Additional Attachments\)](#)

Summary 1572 Financial Disclosure Supplemental Investigator Data Form **Additional Attachments**

Additional Attachments

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Add New

File Name	Description	Upload Date
<input checked="" type="checkbox"/> Sample_File.pdf	Supplemental Information	12/28/2012

**CTEP Annual
Attach
Attachments**




Registration Forms Completed

Sign and Submit Forms

 Help

All your forms have been completed and are assembled for submission. The documents that require your digital signature are link-enabled and you can preview them prior to signing.

Your Submission Includes:

Registration Form	Requires Digital Signature
cv.pdf	
financial_disclosure_form.pdf	
form_1572.pdf	
human_research_certificate.pdf	

Enter your credentials below to digitally sign the documents and submit this registration to the sponsor.

Username

Password

Sign

Close