Sample NCI Investigator Registration Packet

Registration Packet for
Site ID # XXX-000000
Protocol # P-NCI-0000-100
Investigator ID # IP-40001

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Protocol Information and Delegation of Tasks Log (DTL)

PROTOCOL INFORMATION		
PROTOCOL TITLE A Phase 2, open-ended Multicenter, Safety and Efficacy Study of Z01 agents in Patients With Mutant EGFR Non-small Cell Lung Cancer (NSCLC)		
PHASE II	NCTN # 1001	DOCUMENT # P-NCI-0000-100

SITE INFORMATION		
Research Site Name ABC Medical Center	Site ID XXX-000000	Activation Start Date 09/01/2010
Address 2100 Center Lane Suite 2000 Rockville MD USA20850		

SITE PRINCIPAL INVESTIGATOR INFORMATION		
Person ID IP-40001	Name of Principal Investigator Graves, Jeffrey	Primary Site ABC Medical Center
Address One Research Court Suite 200 Rockville MD USA20850		

IRB of Record		
IRB # IRB1234567	IRB Name XYZ Cancer Research Inc.	Address Rockville MD USA20850

Laboratory Information		
CLIA # LAB1234567	Laboratory Name 123 Cancer Laboratory LLC.	Address Rockville MD USA20850

DELEGATION OF TASKS LOG (DTL)

#	Person ID	SUB-INVESTIGATORS	REGISTRATION TYPE / ROLE	RESEARCH TASKS	START DATE/ END DATE
1	IP-10001	Jeffrey Graves	Investigator / Site PI	All Research Tasks	10/21/2014
2	A-30001	Natasha Romanoff	Associate / Site Administrator	DTA	10/21/2014
3	IP-10002	Diana Prince	Investigator / Physician	EAS, ICD. OIC, CPE, AOD, ASD, ATA, TAS, APR, AEA, AER, PDA, SDC, PEN, LSC, ETR, ASE, MRD, DEA, DSO, RS, DAD	10/21/2014
4	AP-20001	Clark Kent	Associate Plus / Nurse Practitioner	OIC, CPE, AOD, ASD, ATA, TAS, APR, AEA, AER, PDA, LSC, DEA, DSO	10/21/2014 to 04/30/2015
5	AP-20002	Peter Parker	Associate Plus / Nurse Practitioner	OIC, CPE, AOD, ASD, ATA, TAS, APR, AEA, AER, PDA, LSC, DEA, DSO	05/01/2015
6	A-30002	Bruce Banner	Associate / CRA	DAD, DEA	10/21/2014

DATE *(mm/dd/yyyy)*	SIGNATURE OF INVESTIGATOR
05/01/2015	The following information states that the identified document has been electronically signed by the Investigator Name: Natasha Romanoff Email: romanoff.natasha@xyz.com Date Signed 05/01/2015 :12:53:54 Signer IP Address 73.191.63.99 Browser Type: Mozilla/5.0

Research Tasks Legend					
DTA	Delegation of Tasks Authority	EAS	Eligibility assessment	ICD	IC discussion
OIC	Obtain informed consent	CPE	Conduct Physical Exams	AOD	Agent Ordering Designee
ASD	Agent Shipping Designee	ATA	Administration of test article	TOA	Toxicity Assessment
APR	Agent Prescription	AEA	AE assessment	AER	AE reporting
PDA	Perform drug accountability	SDC	Source Document Completion	PEN	Patient Enrollment
LSC	Laboratory Specimen Collection/Shipping	ETR	Evaluate study-related test results	ASE	Assessment of primary study endpoints
MRD	Update/maintain regulatory docs	DEA	Data Entry/Access	DSO	Data Sign-off
RS	Regulatory submissions	DAD	Delegation of Tasks Administration		

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SITE PI Information – Jeffrey Graves

SITE PRINCIPAL INVESTIGATOR INFORMATION

Person ID	Name of Principal Investigator	Primary Site
IP-40001	Graves, Jeffrey	ABC Medical Center

Address 1	Address 2
One Research Court	Suite 200

City	State/Province/Region	Country	ZIP or Postal Code
Rockville	MD	USA	20850

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Form 1572

Collection of this information is authorized under 21 CFR 312.53. The primary use is to identify qualified investigators to participate in clinical investigations at the National Cancer Institue. This information may be disclosed to researchers for research purposes, sponsors of clinical trials, the applicable Institutional Review Board, National Cancer Institue, Food and Drug Administrations's Center for Drug Evalaution and Research and Center for Biologics Evaluation and Research, and the Department of Health and Human Services. Submission of this information is voluntary. However, In order to conduct studies in accordance with the relevant regulatory requirements, you must complete all fields.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR
(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART312)
(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014 **Expiration Date: 03/31/2016**

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, FormFDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Principal Investigator			
Graves, Jeffrey			
Address 1		Address 2	
One Research Court		Suite 200	
City	State/Province/Region	Country	ZIP or Postal Code
Rockville	MD	USA	20850

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select **one** of the following.)*

☒ Curriculum Vitae ☐ Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED

Name of Medical School, Hospital, or Other Research Facility	Address
ABC Medical Center	One Research Court Suite 200, Rockville, MD 20850
DEF Medical Center	Two Medical Drive Suite 300, Chantilly, VA 20850
GHI Health Center	Three Health Lane Suite 400, Charlotte, NC 20850
JKL Hospital Center	Four Hospital Boulevard Suite 500, Atlanta, GA 20850

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY

Name of Clinical Laboratory Facility	Address
123 Cancer Laboratory LLC.	Rockville, MD 20850
456 Cancer Laboratory LLC.	Chantilly, VA 20850
798 Cancer Laboratory LLC.	Charlotte, NC 20850

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES)

Name of IRB	Address
IRB1234567 - XYZ Cancer Laboratory LLC.	Rockville, MD 20850
IRB7654321 - UVW Cancer Laboratory LLC.	Chantilly, VA 20850

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

N/A – The National Cancer Institute requires each investigator to submit a separate FDA Form 1572, CV, Supplemental Investigator Data Form (if applicable), and Financial Disclosure Form. Sub-Investigator information will be entered in this Delegation of Tasks Log (DTL)

REFER TO THE DELEGATION OF TASKS LOG (DTL) FOR THE LIST OF SUB-INVESTIGATORS AND THE DELEGATED RESEARCH TASKS

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

I am participating in National Cancer Institute-sponsored clinical trials. I understand that this single FDA Form 1572 will cover my participation in all (one or more) clinical trials under NCI sponsorship (IND and/or funding). I also understand that I am responsible for meeting all the requirements for clinical trials specified by this electronically signed FDA Form 1572 for EACH NCI clinical trial in which I participate.

PSC Publishing Services (301) 443-6740

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8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION.** 1. Check one or both boxes as appropriate.
2. Protocol(s) should not be attached.

☐ 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 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. **

** Refer to item number 7 and the NCI Drug Master File #2803 at FDA for a general outline of planned investigation.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572 STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.
2. Provide curriculum vitae or other statement of qualifications as described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND).

10 and 11. DATE and SIGNATURE OF INVESTIGATOR

The following information states that the identified document has been electronically signed by the Investigator

Name:	Graves, Jeffrey
Email:	Graves.Jeffrey@xyz.com
Date Signed	12/21/2014 :14:11:54
Signer IP Address	73.191.63.99
Browser Type:	Mozilla/5.0

(**WARNING**: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

Sample NCI Investigator Registration Packet

Site PI Sign-off on the Initial Delegation of Tasks Log (DTL)

PROTOCOL INFORMATION

PROTOCOL TITLE

A Phase 2, open-ended Multicenter, Safety and Efficacy Study of Z01 agents in Patients With Mutant EGFR Non-small Cell Lung Cancer (NSCLC)

PHASE	NCTN #	DOCUMENT #yy
II	1001	P-NCI-0000-100yy

SITE INFORMATION

Name	Site ID	Activation Start Date
ABC Medical Center	ABC Medical Center	09/01/2010

Address

2100 Center Lane Suite 2000 Rockville MD USA 20850

SITE PRINCIPAL INVESTIGATOR INFORMATION

Person ID	Name of Principal Investigator	Primary Site
IP-40001	Graves, Jeffrey	ABC Medical Center

Address

One Research Court Suite 200 Rockville MD USA20850

IRB of Record

IRB #	IRB Name	Address
IRB1234567	XYZ Cancer Research Inc.	Rockville MD USA20850

Laboratory Information

CLIA #	Laboratory Name	Address
LAB1234567	123 Cancer Laboratory LLC.	Rockville MD USA20850

DELEGATION OF TASKS LOG (DTL)

#	PERSON ID	SUB-INVESTIGATORS	REGISTRATION TYPE / ROLE	RESEARCH TASKS	START DATE/ END DATE
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4	AP-20001	Clark Kent	Associate / Nurse Practitioner	OIC, CPE, AOD, ASD, ATA, TAS, APR, AEA, AER, PDA, LSC, DEA, DSO	10/21/2014
5	A-30002	Bruce Banner	Associate / CRA	DAD, ATA, PEN, DEA	10/21/2014

COMMITMENTS

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- I agree to personally conduct or supervise the described investigation(s).
- I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.
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- 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.
- I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.
- I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR312.68.
- I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial andcontinuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

SIGNATURE OF INVESTIGATOR: The following information states that the identified document has been electronically signed by the Investigator

Name:	Jeffrey Graves
Email:	graves.jeffrey@xyz.com
Date Signed	10/21/2014 :11:21:54
Signer IP Address	73.191.63.102
Browser Type:	Mozilla/5.0

Research Tasks Legend

DTA	Delegation of Tasks Authority	EAS	Eligibility assessment	ICD	IC discussion
OIC	Obtain informed consent	CPE	Conduct Physical Exams	AOD	Agent Ordering Designee
ASD	Agent Shipping Designee	ATA	Administration of test article	TOA	Toxicity Assessment
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RS	Regulatory submissions	DAD	Delegation of Tasks Administration		

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Fianacial Disclosure Form

OMB No. 0925-0613
Expiration Date: 03/31/2016

Collection of this information is authorized under 21 CFR 54.4. The use of this information is to disclose or certify information concerning the financial interests of the clinical investigators associated with clinical studies. This information may be disclosed to sponsors of clinical trials, National Cancer Institute, Food and Drug Administration's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, and the Department of Health and Human Services. Submission of this information is voluntary, however, in order for us to qualify you to conduct a study in accordance with the relevant, current protocol(s), you must complete all fields.

Public reporting burden 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. **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 (0925-0613). Do not return the completed form to this address.

C O N F I D E N T I A L
FINANCIAL DISCLOSURE FORM

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 CTEP-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 Company(ies) Not Applicable

This form must be signed (original signature required) and dated and submitted with your signed FDA Form 1572 (original signature required) and Supplemental Investigator Data Form as part of your annual CTEP investigator registration packet. 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 Network of which you are a member if CTEP is notified that a clinical trial is being developed by that Network 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 Network administrative staff for additional information.

SIGNATURE OF INVESTIGATOR: The following information states that the identified document has been electronically signed by the Investigator

Name:	Graves, Jeffrey
Email:	Graves.Jeffrey@xyz.com
Date Signed	12/21/2014 :14:11:54
Signer IP Address	73.191.63.99
Browser Type:	Mozilla/5.0

Sample NCI Investigator Registration Packet

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Graves, Jeffrey	Associate Professor of Psychology
eRA COMMONS USER NAME (credential, e.g., agency login) gravesj	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of California, Berkeley	B.S.	05/90	Psychology
University of Vermont	Ph.D.	05/96	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/98	Public Health and Epidemiology

Personal Statement

The goal of the proposed research is to investigate the interaction between drug abuse and normal aging processes. Specifically, we plan to measure changes in cognitive ability and mental and physical health across a five-year period in a group of older drug users and matched controls. I have the expertise, leadership and motivation necessary to successfully carry out the proposed work. I have a broad background in psychology, with specific training and expertise in key research areas for this application. As a postdoctoral fellow at Berkeley, I carried out ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. At the Division of Intramural Research at the National Institute on Drug Abuse (NIDA), I expanded my research to include neuropsychological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work, and I have chosen co-investigators (Drs. Gryczynski and Newlin) who provide additional expertise in cognition, gerontology and geriatrics. During 2005- 2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support. In summary, I have a demonstrated record of accomplished and productive research projects in an area of high relevance for our aging population, and my expertise and experience have prepared me to lead the proposed project.

Positions and Honors

Positions and Employment

1998-2000 Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD 2000-2002 Lecturer, Department of Psychology, Middlebury College, Middlebury, VT

2001- Consultant, Coastal Psychological Services, San Francisco, CA

2002-2005 Assistant Professor, Department of Psychology, Washington University, St. Louis, MO

2007- Associate Professor, Department of Psychology, Washington University, St. Louis, MO

Other Experience and Professional Memberships

1995- Member, American Psychological Association
1998- Member, Gerontological Society of America
1998- Member, American Geriatrics Society
2000- Associate Editor, Psychology and Aging
2003- Board of Advisors, Senior Services of Eastern Missouri
2003-05 NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2007-11 NIH Risk, Adult Addictions Study Section, member

Honors

2003 Outstanding Young Faculty Award, Washington University, St. Louis, MO 2004 Excellence in Teaching, Washington University, St. Louis, MO

2009 Award for Best in Interdisciplinary Ethnography, International Ethnographic Society

Selected Peer-reviewed Publications (Selected from 42 peer-reviewed publications)

Most relevant to the current application

1. Graves, J (2004). Independent living, physical disability and substance abuse among the elderly. Psychology and Aging, 23(4), 10-22.
2. Graves, J. (2007). Substance abuse and mental health among community- dwelling elderly. International Journal of Geriatric Psychiatry, 24(9), 1124-1135.
3. Graves, J (2008). Predicting the substance-abuse treatment needs of an aging population. American Journal of Public Health, 45(2), 236-245. PMCID: PMC9162292
4. Graves, J (2009). Brain imaging in methamphetamine abusers across the life-span. Gerontology, 46(3), 122-145.
5. Graves, J (2009). Successful intervention models for older drug-abusers: Research across the life-span. American Psychologist, in press. NIHMSID: NIHMS99135

Additional recent publications of importance to the field (in chronological order)

1. Graves, J (2002). Community based participatory research with late-life addicts. American Journal of Alcohol and Drug Abuse, 15(3), 222-238.
2. Graves, J (2003). Policy implications of genetic transmission of alcohol and drug abuse in female nonusers. International Journal of Drug Policy, 30(5), 46-58.
3. Graves, J. (2004). Early-life family and community characteristics and late-life substance abuse. Journal of Applied Gerontology, 28(2),26-37.
4. Graves, J. (2005). The effect of social support networks on morbidity among elderly substance abusers. Journal of the American Geriatrics Society, 57(4), 15-23.
5. Graves, J. (2005). Aging out of methadone treatment. American Journal of Alcohol and Drug Abuse, 15(6), 134-149.
6. Graves, J. (2007). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. Addiction, 104(9), 1436-1606. PMCID: PMC9000292
7. Graves, J. (2007). Randomized clinical trial of cotinine in older nicotine addicts. Age and Ageing, 38(2), 9-23. PMCID: PMC9002364
8. Graves, J (2008). The aging addict: ethnographic profiles of the elderly drug user. NY, NY: W. W. Norton & Company.
9. Graves, J. (2009). Contrasting ethnicity with race in the older alcoholic. The Journals of Gerontology Series B: Psychological Sciences and Social Sciences, in press. PMCID: PMC Journal – In Process.
10. Graves, J. (2009). Intervening successfully with the older methadone patient. Journal of Applied Gerontology, 13(4), 67-79.

Research Support Ongoing

Research Support

R01 DA942367-03 Graves, J 09/01/08-08/31/13

Health trajectories and behavioral interventions among older substance abusers

The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.

Role: PI

R01 MH922731-05 Graves, J 12/15/07-11/30/12

Physical disability, depression and substance abuse in the elderly

The goal of this study is to identify disability and depression trajectories and demographic factors associated with substance abuse in an independently-living elderly population.

Role: Co-Investigator

Faculty Resources Grant, Washington University 08/15/09-08/14/11 Opiate Addiction Database

The goal of this project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.

Completed Research Support

K02 AG442898 Graves, J 02/01/02-01/31/05

Drug Abuse in the Elderly

Independent Scientist Award: to develop a drug addiction research program with a focus on substance abuse among the elderly.

Role: PI

R21 AA998075 Graves, J 01/01/02-12/31/04

Community-based intervention for alcohol abuse

The goal of this project was to assess a community-based strategy for reducing alcohol abuse among older individuals.

Role: PI

SIGNATURE OF INVESTIGATOR: The following information states that the identified document has been electronically signed by the Investigator

Name:	Graves, Jeffrey
Email:	Graves.Jeffrey@xyz.com
Date Signed	12/21/2014 :14:11:54
Signer IP Address	73.191.63.99
Browser Type:	Mozilla/5.0

Sample NCI Investigator Registration Packet

Training – Protecting Human Research Participants

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that *Jeffrey Graves* successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: *01/01/2014*

Certification Number: *99999999*

Statement of Credit

Name of Learner: Jeffrey Graves
Title of Activity: Fundamental Good Clinical Practice Training and Assessment for Support Staff
4
Credit Awarded: .3 CEUs/3 Hours
Universal Activity Number: 0778-0000-12-056-L01-P
Type of Activity: Knowledge

Sponsored by:

ABC Education Services

John Doe

Authorized Continuing Education Administrator

01/01/2014

Date

ABC Education Services is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Sample NCI Investigator Registration Packet

Sub-investigator Information – Diana Prince

SUB-INVESTIGATOR INFORMATION

Person ID	Name of Principal Investigator	Primary Site
IP-10002	Prince, Diana	XYZ Medical Center

Address 1	Address 2
One Research Court	Suite 200

City	State/Province/Region	Country	ZIP or Postal Code
Rockville	MD	USA	20850

ROLE Physician

DELEGATED RESEARCH TASKS

EAS, ICD. OIC, CPE, AOD, ASD, ATA, TAS, APR, AEA, AER, PDA, SDC, PEN, LSC, ETR, ASE, MRD, DEA, DSO, RS, DAD

Research Tasks Legend					
DTA	Delegation of Tasks Authority	EAS	Eligibility assessment	ICD	IC discussion
OIC	Obtain informed consent	CPE	Conduct Physical Exams	AOD	Agent Ordering Designee
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Fianacial Disclosure Form

OMB No. 0925-0613
Expiration Date: 03/31/2016

Collection of this information is authorized under 21 CFR 54.4. The use of this information is to disclose or certify information concerning the financial interests of the clinical investigators associated with clinical studies. This information may be disclosed to sponsors of clinical trials, National Cancer Institute, Food and Drug Administration's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, and the Department of Health and Human Services. Submission of this information is voluntary, however, in order for us to qualify you to conduct a study in accordance with the relevant, current protocol(s), you must complete all fields.

Public reporting burden 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. **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 (0925-0613). Do not return the completed form to this address.

C O N F I D E N T I A L
FINANCIAL DISCLOSURE FORM

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 CTEP-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 Company(ies) Not Applicable

This form must be signed (original signature required) and dated and submitted with your signed FDA Form 1572 (original signature required) and Supplemental Investigator Data Form as part of your annual CTEP investigator registration packet. 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 Network of which you are a member if CTEP is notified that a clinical trial is being developed by that Network 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 Network administrative staff for additional information.

SIGNATURE OF INVESTIGATOR: The following information states that the identified document has been electronically signed by the Investigator

Name:	Prince, Diana
Email:	Prince.Diana@xyz.com
Date Signed	01/15/2015 :14:11:54
Signer IP Address	73.191.63.98
Browser Type:	Mozilla/5.0

Sample NCI Investigator Registration Packet

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Prince, Diana	Site Principal Investigator / Sub-Investigator
eRA COMMONS USER NAME (credential, e.g., agency login) princed	

LICENSE INFORMATION

PROFESSION	LICENSE #	STATE	ISSUE DATE	EXPIRATION DATE	STATUS
MEDICAL DOCTOR	XX99999	MD	06/17/2004	1/31/2016	CLEAR/ACTIVE

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Maryland	B.S.	05/1994	Internal Medicine
University of Maryland	MD	05/1998	Doctor of Medicine

Positions and Honors

Positions and Employment

1999-2004 Staff Pediatrition, Pediatric Hospital of Maryland, Germantown MD
2004-2010 Private Practive Pediatrician, Rockville, MD
2010-Present Head Pediatrician, Barton Hospital, VA

Other Experience and Professional Memberships

2005-2014- Member, American Academy of Pediatrics

SIGNATURE OF INVESTIGATOR: The following information states that the identified document has been electronically signed by the Investigator

Name: Prince, Diana
Email: Prince.Diana@xyz.com
Date Signed 01/15/2015 :14:11:54
Signer IP Address 73.191.63.98
Browser Type: Mozilla/5.0

Sample NCI Investigator Registration Packet

Training – Protecting Human Research Participants

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that *Diana Prince* successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: *01/01/2014*

Certification Number: *11111111*

Statement of Credit

Name of Learner: *Diana Prince*

Title of Activity: Fundamental Good Clinical Practice Training and Assessment for Support Staff

Credit Awarded: .3 CEUs/3 Hours
Universal Activity Number: 0778-0000-12-056-L01-P
Type of Activity: Knowledge

Sponsored by:

ABC Education Services

John Doe

Authorized Continuing Education Administrator

01/01/2014

Date

ABC Education Services is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Sample NCI Investigator Registration Packet

Sub-investigator Information – Clark Kent

SUB-INVESTIGATOR INFORMATION

Person ID	Name of Principal Investigator	Primary Site
AP-20001	Kent, Clark	XYZ Medical Center

Address 1	Address 2
One Research Court	Suite 200

City	State/Province/Region	Country	ZIP or Postal Code
Rockville	MD	USA	20850

ROLE Nurse Practioner

DELEGATED RESEARCH TASKS

OIC, CPE, AOD, ASD, ATA, TAS, APR, AEA, AER, PDA, LSC, DEA, DSO

Research Tasks Legend					
DTA	Delegation of Tasks Authority	EAS	Eligibility assessment	ICD	IC discussion
OIC	Obtain informed consent	CPE	Conduct Physical Exams	AOD	Agent Ordering Designee
ASD	Agent Shipping Designee	ATA	Administration of test article	TOA	Toxicity Assessment
APR	Agent Prescription	AEA	AE assessment	AER	AE reporting
PDA	Perform drug accountability	SDC	Source Document Completion	PEN	Patient Enrollment
LSC	Laboratory Specimen Collection/Shipping	ETR	Evaluate study-related test results	ASE	Assessment of primary study endpoints
MRD	Update/maintain regulatory docs	DEA	Data Entry/Access	DSO	Data Sign-off
RS	Regulatory submissions	DAD	Delegation of Tasks Administration		

Sample NCI Investigator Registration Packet

Fianacial Disclosure Form

OMB No. 0925-0613
Expiration Date: 03/31/2016

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C O N F I D E N T I A L
FINANCIAL DISCLOSURE FORM

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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?**

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Pharmaceutical Company(ies) Not Applicable

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SIGNATURE OF INVESTIGATOR: The following information states that the identified document has been electronically signed by the Investigator

Name:	Kent, Clark
Email:	Kent.Clark@xyz.com
Date Signed	01/15/2015 :14:11:54
Signer IP Address	73.191.63.102
Browser Type:	Mozilla/5.0

Sample NCI Investigator Registration Packet

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Kent, Clark	Nurse Practitioner
eRA COMMONS USER NAME (credential, e.g., agency login) kentc	

LICENSE INFORMATION

PROFESSION	LICENSE #	STATE	ISSUE DATE	EXPIRATION DATE	STATUS
Nursing Education Program - RN	RN99999	MD	06/17/2004	1/31/2016	CLEAR/ACTIVE

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Maryland	B.S.	05/1994	Internal Medicine
University of Maryland	MD	05/1998	Doctor of Medicine

Positions and Honors

Positions and Employment

1999-2004 Oncology Nurse, Pediatric Hospital of Maryland, Germantown MD
2004-2010 Oncology Nurse,, St. Joseph Health Center, NY
2010-Present Oncology Nurse, City Center Hospital, NY

Other Experience and Professional Memberships

2005-2014- Member, Oncology Nursing Society

SIGNATURE OF INVESTIGATOR: The following information states that the identified document has been electronically signed by the Investigator

Name: Kent, Clark
Email: Kent.Clark@xyz.com
Date Signed 01/15/2015 :14:11:54
Signer IP Address 73.191.63.102
Browser Type: Mozilla/5.0

Sample NCI Investigator Registration Packet

Training – Protecting Human Research Participants

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that *Clark Kent* successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: *01/01/2014*

Certification Number: *88888888*

Statement of Credit

Name of Learner: *Clark Kent*

Title of Activity: Fundamental Good Clinical Practice Training and Assessment for Support Staff

Credit Awarded: .3 CEUs/3 Hours
Universal Activity Number: 0778-0000-12-056-L01-P
Type of Activity: Knowledge

Sponsored by:

ABC Education Services

John Doe

Authorized Continuing Education Administrator

01/01/2014

Date

ABC Education Services is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Sample NCI Investigator Registration Packet

Sub-investigator Information – Peter Parker

SUB-INVESTIGATOR INFORMATION

Person ID	Name of Principal Investigator	Primary Site
AP-20001	Kent, Clark	XYZ Medical Center

Address 1	Address 2
One Research Court	Suite 200

City	State/Province/Region	Country	ZIP or Postal Code
Rockville	MD	USA	20850

ROLE Nurse Practioner

DELEGATED RESEARCH TASKS

OIC, CPE, AOD, ASD, ATA, TAS, APR, AEA, AER, PDA, LSC, DEA, DSO

Research Tasks Legend					
DTA	Delegation of Tasks Authority	EAS	Eligibility assessment	ICD	IC discussion
OIC	Obtain informed consent	CPE	Conduct Physical Exams	AOD	Agent Ordering Designee
ASD	Agent Shipping Designee	ATA	Administration of test article	TOA	Toxicity Assessment
APR	Agent Prescription	AEA	AE assessment	AER	AE reporting
PDA	Perform drug accountability	SDC	Source Document Completion	PEN	Patient Enrollment
LSC	Laboratory Specimen Collection/Shipping	ETR	Evaluate study-related test results	ASE	Assessment of primary study endpoints
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Sample NCI Investigator Registration Packet

Fianacial Disclosure Form

OMB No. 0925-0613
Expiration Date: 03/31/2016

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C O N F I D E N T I A L
FINANCIAL DISCLOSURE FORM

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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?**

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Pharmaceutical Company(ies) Not Applicable

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SIGNATURE OF INVESTIGATOR: The following information states that the identified document has been electronically signed by the Investigator

Name:	Kent, Clark
Email:	Kent.Clark@xyz.com
Date Signed	01/15/2015 :14:11:54
Signer IP Address	73.191.63.102
Browser Type:	Mozilla/5.0

Sample NCI Investigator Registration Packet

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
PArker, Peter	Nurse Practitioner
eRA COMMONS USER NAME (credential, e.g., agency login) parkerp	

LICENSE INFORMATION

PROFESSION	LICENSE #	STATE	ISSUE DATE	EXPIRATION DATE	STATUS
Nursing Education Program - RN	RN99998	MD	06/17/1990	1/31/2016	CLEAR/ACTIVE

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Macomb Community College, Macomb, MI	B.S.	05/1990	Nursing

Positions and Honors

Positions and Employment

1999-2004 Oncology Nurse, Pediatric Hospital of Maryland, Germantown MD
2004-2010 Oncology Nurse,, St. Joseph Health Center, NY
2010-Present Oncology Nurse, City Center Hospital, NY

Other Experience and Professional Memberships

2005-2014- Member, Oncology Nursing Society

SIGNATURE OF INVESTIGATOR: The following information states that the identified document has been electronically signed by the Investigator

Name: Parker, Peter
Email: Parker.Peter@xyz.com
Date Signed 01/15/2015 :14:11:54
Signer IP Address 73.191.63.103
Browser Type: Mozilla/5.0

Sample NCI Investigator Registration Packet

Training – Protecting Human Research Participants

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that *Peter Parker* successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: *01/01/2014*

Certification Number: *77777777*

Statement of Credit

Name of Learner: *Peter Parker*
Title of Activity: Fundamental Good Clinical Practice Training and Assessment for Support Staff

Credit Awarded: .3 CEUs/3 Hours
Universal Activity Number: 0778-0000-12-056-L01-P
Type of Activity: Knowledge

Sponsored by:

ABC Education Services

John Doe

Authorized Continuing Education Administrator

01/01/2014

Date

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