Research Administration and Compliance Meeting
Tuesday, August 20, 2013, 1:00 – 3:00 p.m.
Larrick Hall, Court End Ballroom B

Agenda

General Items/Updates

- FY2012-13 Award and Expenditure Reports
- VA SRA Chapter Meeting – 2014

Integrity and Ethics Updates (ORIE)

- AIRS: Annual Update – Final Report

Subjects Protection Updates (ORSP)

- RAMS-IRB Update
- Controlled Substances Policy and Update

Clinical Research Services Update (CRS)

- Cost Coverage Analysis Training – August 29, 2013
- VCU Vision for Clinical Trials - http://www.cctr.vcu.edu/clinicalresearch/vision.html

Sponsored Programs Updates (OSP)

- ASSIST
- Commons User IDs for Graduate and Undergraduate students on NIH Projects
- Clinical Trials.gov Registration and Reporting Requirements

Grants & Contracts Updates (G&C)

- NCURA FRA Training – Reminder
- G&C/Effort Staffing changes
- ECRT Clinical/Semi-Annual Certification Period
- IBS Compensation Codes – New Link to be added to website

Future Meeting Dates, 1-3 p.m.

- October 30, 2013, Larrick Court End B
- February 19, 2014, Larrick Court End A
- April 24, 2014, Larrick Court End A

Research Administration and Compliance Meeting

August 2013

FY 13 Awards and Expenditures

Awards (as of 8/16/13) - $244,804,615

Expenditures - $196,015,000

(-2.7%)

VA SRA Chapter Meeting

- May 2014 at VCU
- Additional information

VCUeRA Status

- Grants.gov moving to Adobe Form C
- Upgrade to VCUeRA week of August 26
- Unsure of impact
- Using list serves for updates

IDPs for Graduate Students & Postdocs

- NIH has issued NOT-OD-13-093
- Encourages institutions to develop Individual Development Plans (IDPs) for graduate students and postdoctoral researchers (including scholars, trainees and fellows, and individuals in other postdoctoral positions) supported by NIH awards by October 2014
- NIH encourages grantees to develop institutional policies requiring an IDP for NIH-supported graduate students and postdocs by October 1, 2014
- For IDPs already in place, report via RPPR as of October 18, 2013
- Trainees using 2590 report under 5.1.6 Progress Report Summary

Controlled Substances

- Updated interim policy now posted
- Comments requested through September 9
- DAR no longer permitted to provide substances to our faculty
- Notice being provided separately to those individuals
- Application process usually takes 2-3 months so encourage faculty to begin now
- VCU to be compliant on January 1, 2014

Clinical Research Billing/Coverage Analysis Training

Session One

7 to 8:30 a.m., The Learning Center, Main Hospital

Primary audience: Prinicipal investigators, department administrators

Session Objectives:

* Overview of regulatory risks of clinical research billing non-compliance
* The importance of a Coverage Analysis (CA) for compliance
* An overview of Medicare rules for billing during clinical research studies
* How the language of the Informed Consent Form influences what can be billed to insurance
* How the budget structure influences what can be billed to insurance
* The role investigators and coordinators play in ensuring compliant research billing

Clinical Research Billing/Coverage Analysis Training

Session Two

9 a.m. to 12 p.m., Larrick Student Center, End Ballroom

Primary audience: Investigators, coordinators, billing staff (physician and hospital), school, central administration, ancillary departments (lab, radiology, pharmacy)

Session Objectives:

* Overview of Medicare rules for billing clinical research studies

* What does Medicare mean by a “qualifying clinical trial?"

* What does Medicare mean by “routine costs?”

* The importance of the research coordinator in ensuring clinical research billing is compliant

* Tips on protocol design for investigator-initiated studies to improve budgeting and billing

* The role of the study calendar in clinical research billing

* Facilitating communications during the research study

Clinical Research Billing/Coverage Analysis Training

Session Three

1 to 3 p.m., Larrick Student Center, End Ballroom

Primary audience: Investigators, coordinators, research office staff, any others involved in developing or interpreting coverage analysis

Session Objectives:

* Introduction to the Coverage Analysis: Purposes
* Review of forms needed
* Step 1: Draft a grid
* Step 2: Review ICF
* Step 3: Review CTA/Budget
* Step 4: QCT Analysis
* Step 5: Which items and services are “routine costs?”
* Step 6: How to document reasoning
* Step 7: Coding the CA

VIRGINIA COMMONWEALTH UNIVERSITY

VCU Make it real.

Center for Clinical and Translational Research

Clinical Research Administration Update

RACM - August 20, 2013

1. **VCU Vision - Enterprise-Wide Clinical Trials**
   (http://www.cctr.vcu.edu/clinicalresearch/vision.html**)**

2. **OnCore** (VCU's enterprise-wide clinical trials management system):
   a. **About OnCore:** An OnCore website has been developed and should go live this week via CCTR. This site will include access information, requirements for use, roll-out process, contact information, training, tips, and links to unique school/unit requirements (as available). See http://www.cctr.vcu.edu/clinicalresearch/index.html
   b. **System Roll-Out:** ongoing process, began with MCC, now going through SOM following their preferred sequence. Then, remaining schools will be added as needed.
   c. **Written Policy in Development:** to establish clear requirements OnCore use, will be posted to the OnCore website.

3. **Leadership Update-**
   a. **Clinical Research Advisory Board (CRAB)** is a new group planned for advising on process and policy changes influencing VCU's clinical research pipeline in order to improve communications, transparency, and efficiency. Members of the ReDAC will nominate this Board.
   b. The new **VCU Clinical Research Information Officer** (CCTR-BIC) will join us Sept. 1 and will oversee the development of informatics related to clinical research (including OnCore).
   c. The full-time **Executive Director for Clinical Research Services** (CCTR-CRS) search appears to be at the final stage.

4. **New Pre-Award Clinical Trial Process Initiatives** -
   a. Clinical Research Cost Coverage Analysis: Training August 29. Contact Dr. Ripley at eripley@mcvh-vcu.edu with questions or register at https://redcap.vcu.edu/rc/surveys/?s=o7JKda
   b. Looking ahead: processes are underway to improve clarity and transparency by establishing:
      - Clinical Trial Budget Development Standards
      - Clinical Trials Budget Negotiation Standards

Research Administration & Compliance Meeting

August 20, 2013

Annie Publow, Director, OSP,
Government/NonProfit

Office of Sponsored Programs (OSP) Government/Nonprofit Updates

- Application Submission System & Interface for Submission Tracking (ASSIST)

ASSIST: What and Why?

The What: ASSIST (Application Submission System & Interface for Submission Tracking) is a web-based system that NIH has created for multi-project proposal preparation, submission and tracking

The Why: To allow for electronic submission of multi-project proposal submissions (which have not been possible up until now)

- N.B. "Single-project" proposal submissions are currently submitted (through VCUeRA for VCU) to Grants.gov and will continue to be submitted this way

The How: **Agency specific web system**

What registrations are needed to utilize ASSIST?

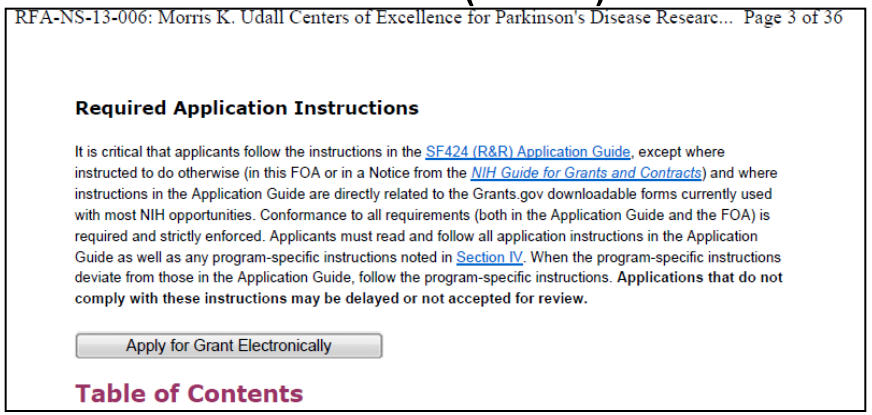
- **Grants.gov** institutional registration →VCU √
- **eRA Commons** (aka NIH website) institutional registration →VCU √
- eRA Commons individual registration, aka "Commons ID" → New PI's will need. Existing NIH PI's already have√
- Central Contractor Registry (CCR) has been replaced by **System for Awards Management** (SAM) →VCU √

Limited List of Important Considerations (when using ASSIST)-VCU specific

- These multi-project NIH submissions will not be prepared or submitted through VCUeRA. (VCUeRA still only for single-project submissions.)
- All multi-project NIH submissions prepared and submitted through ASSIST require an advance PT number, Internal Approval Form, COI reporting through AIRS, etc.
- Any proposed subawardees must still provide “mini-package” and completed and signed VCU Subrecipient Commitment Form

Limited List of Important Considerations (when using ASSIST)

- The application package will utilize the SF424 formset (what we use in VCUeRA)
- Proposed subawardees do not have to be registered in SAM or Grants.gov. DUNS is also requested but optional (use 000000000 if no DUNS available.)
- Download application package from Funding Opportunity Announcement (FOA)-not using Code of Federal Domestic Assistance (CFDA) number


RFA-NS-13-006: Morris K. Udall Centers of Excellence for Parkinson's Disease Researc... Page 3 of 36

Required Application Instructions

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*) and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

Apply for Grant Electronically

Table of Contents

GRANTS & FUNDING

Electronic Grants
Applying Electronically
Applying Electronically to Multi-project Applications
- Prepare to Apply & Register
- Find an Opportunity & Initiate Application
- Prepare & Submit an Application
- Track & View Application

Avoiding Common Errors
Frequently Asked Questions
Training
Resources
Finding Help
Site Map
eRA Commons
Intranet Link (NIH Staff Only)

Grants Basics

Submitting a Multi-project Application

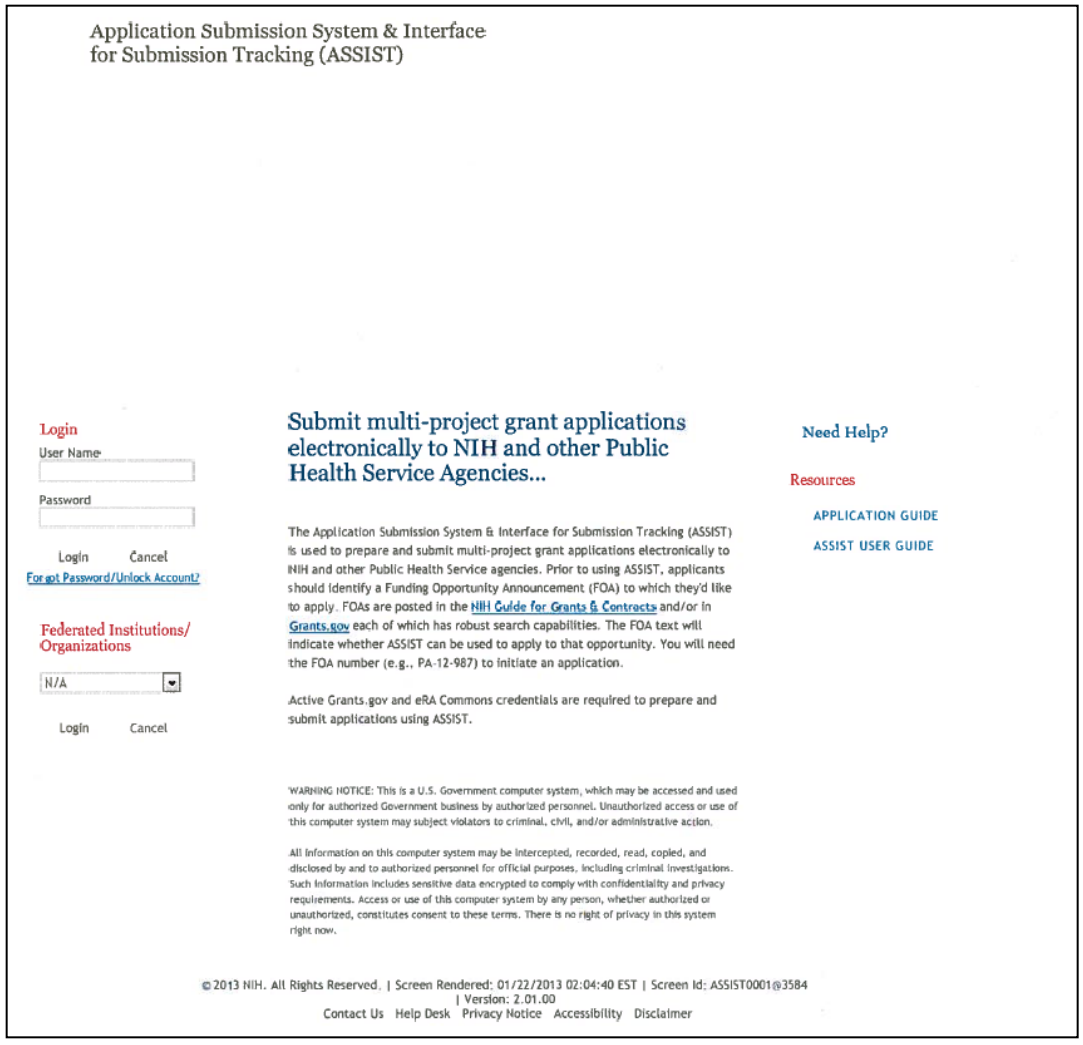
By Jan 2014 NIH's multi-project applications will transition to electronic submission through a new on-line application system called ASSIST. Between now and Sept 2013 NIH will be piloting the system with a handful of funding opportunity announcements.

Learn more about the transition timeline and the ASSIST system.

Electronic Application Process

Make Sure To...

- **Use ASSIST only if required by the FOA.**
- **Register early!** Organizational registration in DUNS, SAM, Grants.gov and eRA Commons is required, can take 6 weeks or more and MUST be completed before the application due date. Learn more about registration requirements.
  - SAM requires annual renewal to maintain an active registration.
  - PIs must be registered and affiliated with the applicant organization in eRA Commons.
  - ASSIST users must be eRA Commons registered.
- **Carefully follow the requirements** found in the application guide and funding opportunity announcement. Instructions in the FOA supersede those found in the application guide.
- **Submit early.** Reduce stress by submitting well ahead of the due date.



- ASSIST is a different system than eraCommons
- ASSIST uses eraCommons log in credentials
- Role in eraCommons will be your role in ASSIST

Limited List of Important Considerations (when using ASSIST)

- Attachments must be PDF (generated outside of ASSIST system.)
- Research Plan must comply with page limitations: create all elements of research plan as a single document and split into section pdf's when final, then upload.
- Reference letters are only permitted when specifically requested in the FOA
- The PI prepares the application and the SO (Signing Official), aka OSP reviews and submits.

Limited List of Important Considerations (when using ASSIST)

- There is a common application format for all multi-project applications to include:
  - A single Overall Component (summary)
  - Additional Components (e.g. Admin Core, Project Cores #1, #2, etc., FOA-specific cores, etc.)
- Components of the same type will appear in the order they are created, i.e. first project core entered will be #1, second #2, etc. –Plan ahead!!

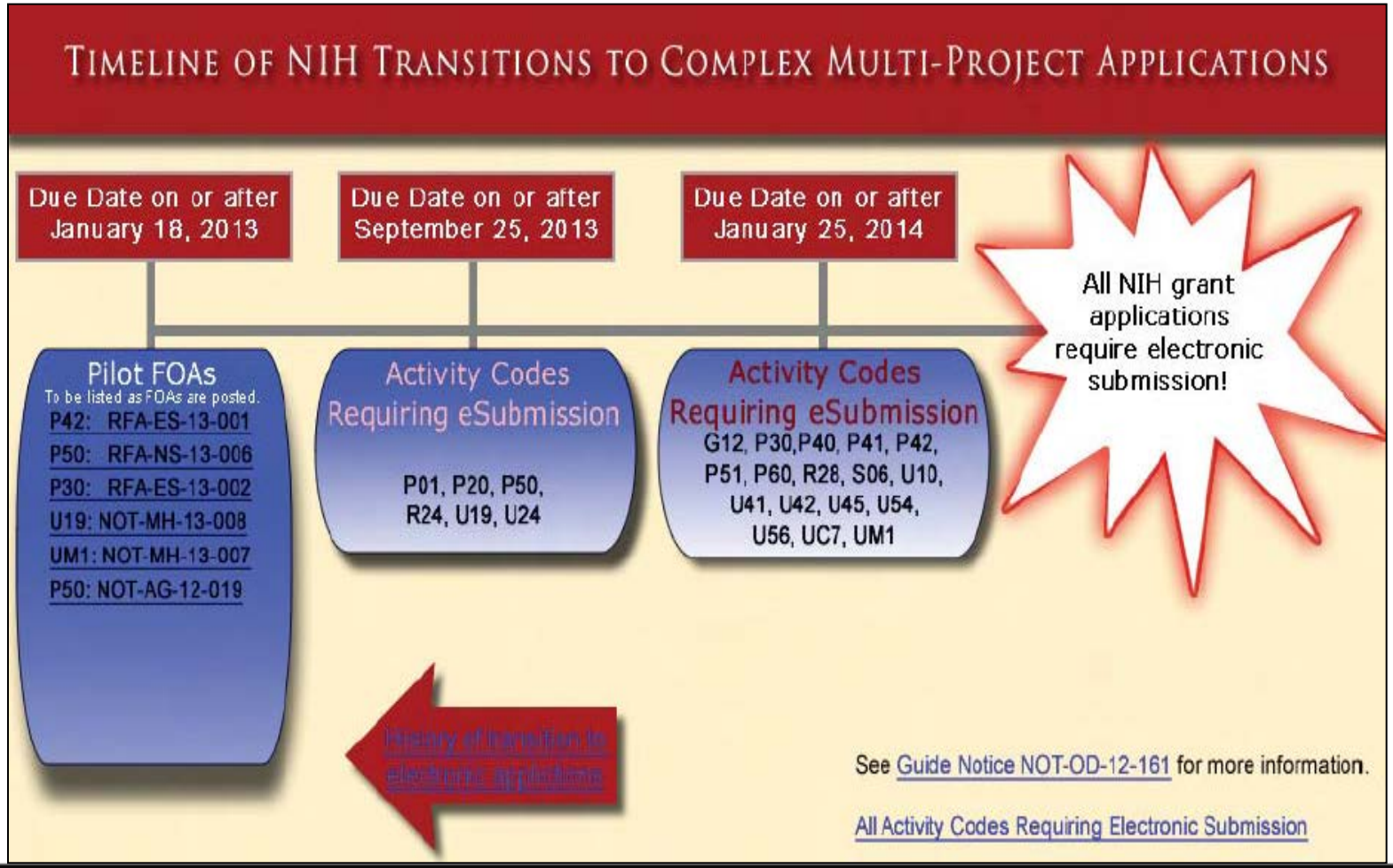
Limited List of Important Considerations (when using ASSIST)

- ASSIST checks applications against both federal-wide and NIH business rules
  - ASSIST checks applications data as it is entered against the rules defined by Grants.gov for each form
  - ASSIST provides the option to “Validate” the application against NIH’s agency-specific business rules prior to submission
  - ASSIST checks for the most frequent Grants.gov rejection errors prior to submission

Limited List of Important Considerations (when using ASSIST)

- On-time submission is no later than 5:00pm on the deadline date.
- Submitted proposals can be tracked through Grants.gov and then, once accepted by NIH, in eRA Commons (just like with VCUeRA submissions now.)
- Once uploaded to eRA Commons, the PI will be able to view the transmission for two days during which time the proposal may be rejected by the SO. The proposal may be corrected and resubmitted only so long as the deadline has not passed.

NIH Transition Dates to ASSIST



Helpful links for Multi-Project Applications using ASSIST

(and identification of sources)

- NIH- Submitting a Multi-Project Application: http://grants.nih.gov/grants/ElectronicReceipt/com_index.htm
- ASSIST FAQs: http://grants.nih.gov/grants/ElectronicReceipt/faq_full.htm#prepare

Clinical Trial Registration Requirements

Melanie Wiggins
Director, OSP-Industry
August 20, 2013

What are the requirements for registration of clinical trials?

Per VCU Policy*, we follow two basic registration requirements:

http://www.assurance.vcu.edu/Policy%20Library/Clinical%20Trials%20Protocol%20Registration.pdf

1. **Pre-registration (prior to subject enrollment)** of all clinical trials regardless of funding in compliance with International Committee of Medical Journal Editor (ICMJE) requirements to ensure protection of publication in their journals. VCU has endorsed using ClinicalTrials.gov since 2005.
2. Compliance with Food and Drug Administration Amendments Act (FDAAA) of 2007 (Title VIII of PL 110-85) for **registration and results reporting of Applicable Clinical Trials** using ClinicalTrials.gov.

* VCU Clinical Trials Registration Policy is currently under revision

NIH requires certification of compliance with FDAAA on grant and progress report forms for grants supporting an Applicable Clinical Trial.

"The NIH encourages registration and results reporting for **all NIH-supported clinical trials**, regardless of whether or not they are subject to FDAAA."
http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more about clinical studies and about this site, including relevant history, policies, and laws.

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

ClinicalTrials.gov currently lists 150,694 studies with locations in all 50 states and in 185 countries.

Text Size

Search for Studies

Example: "Heart attack" AND "Los Angeles"

Search

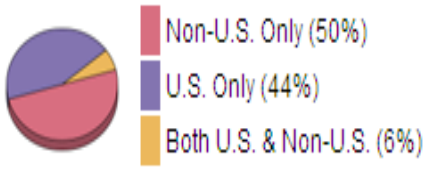
Advanced Search | See Studies by Topic

See Studies on a Map

Search Help

- How to search
- How to find results of studies
- How to read a study record

Locations of Recruiting Studies



Total N = 30,804 studies

Data as of August 18, 2013

- See more trends, charts, and maps

For Patients & Families

- How to find studies
- See studies by topic
- Learn about clinical studies
- Learn more...

For Researchers

- How to submit studies
- Download content for analysis
- About the results database
- Learn more...

For Study Record Managers

- Why register?
- How to register study records
- FDAAA 801 Requirements
- Learn more...

Learn More

- ClinicalTrials.gov Online Training
- Glossary of common site terms

For the Press

Using our RSS Feeds

Clinical Trial Definitions – ICMJE vs FDAAA

- **ICMJE:** A **clinical trial** is "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes". A health-related intervention includes "any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes)."
- Includes Phase 1 studies

- **FDAAA – Applicable Clinical Trials** include :
- **Trials of drugs and biologics.** Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation
- **Trials of devices.** 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) pediatric postmarket surveillance required by FDA
- FDA regulated means conducted in US, under an IND/IDE or manufactured in US. http://clinicaltrials.gov/ct2/manage-recs/fdaaa

Example of a Clinical Trial

This study is currently recruiting participants.

Verified July 2013 by Virginia Commonwealth University

Sponsor:
Virginia Commonwealth University

Collaborator:
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Information provided by (Responsible Party):
Virginia Commonwealth University

ClinicalTrials.gov Identifier:
NCT01620983

First received: June 13, 2012
Last updated: July 24, 2013
Last verified: July 2013
History of Changes

Full Text View | **Tabular View** | **No Study Results Posted** | Disclaimer | How to Read a Study Record

Purpose

Patients undergoing knee replacement surgery and who have high levels of pain catastrophizing are at risk for poor outcome. The clinical trial is designed to determine if a pain coping skills training intervention delivered by physical therapists and supervised by psychologists is more effective at reducing pain and improving function and is more cost effective than arthritis education or usual care.

Condition	Intervention	Phase
Knee Osteoarthritis	Behavioral: Pain Coping Skills Training Behavioral: Arthritis Education Other: Usual Care	Phase 3

Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Knee Arthroplasty Pain Coping Skills Training (KASTPain): A Randomized Trial

This study is currently recruiting participants.

Verified August 2013 by Virginia Commonwealth University

Sponsor:
Virginia Commonwealth University

Collaborator:
Massey Cancer Center

Information provided by (Responsible Party):
Virginia Commonwealth University

ClinicalTrials.gov Identifier:
NCT01075113

First received: February 19, 2010
Last updated: August 12, 2013
Last verified: August 2013
History of Changes

Purpose

This phase I trial is studying the side effects and best dose of vorinostat when given together with sorafenib tosylate in treating patients with advanced liver cancer. Sorafenib tosylate and vorinostat may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth or by blocking blood flow to the tumor. Giving sorafenib tosylate together with vorinostat may kill more tumor cells.

Condition	Intervention	Phase
Liver Cancer	Drug: sorafenib tosylate Drug: vorinostat	Phase 1

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Endpoint Classification: Safety Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase I Study of Sorafenib and Vorinostat in Advanced Hepatocellular Carcinoma

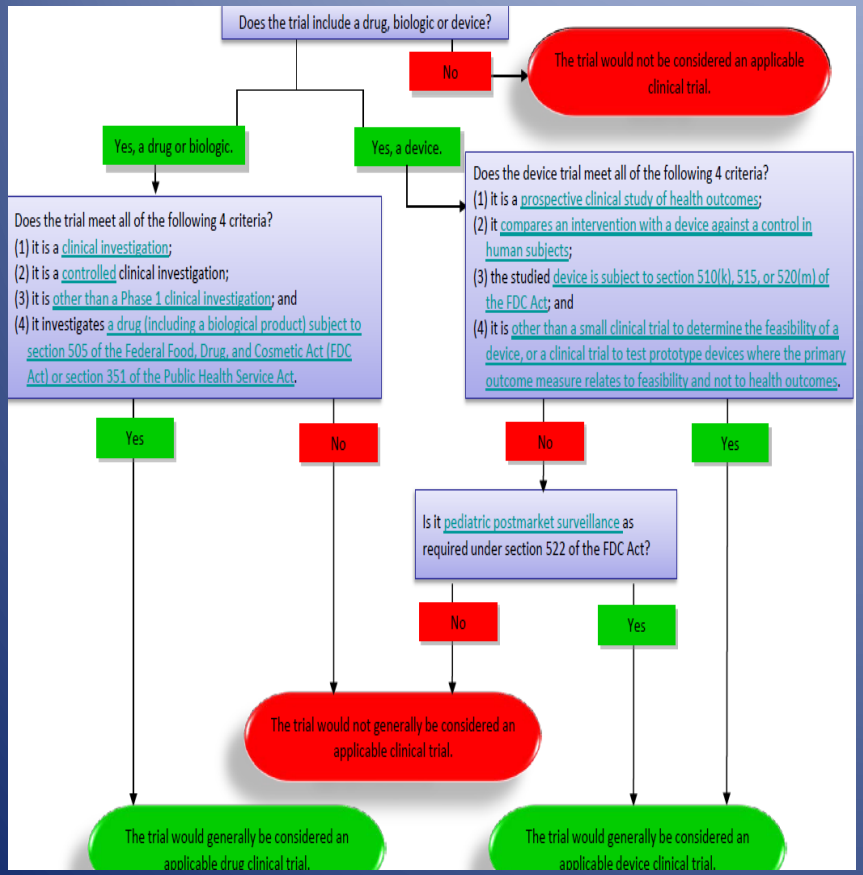
Identifying an Applicable Clinical Trial

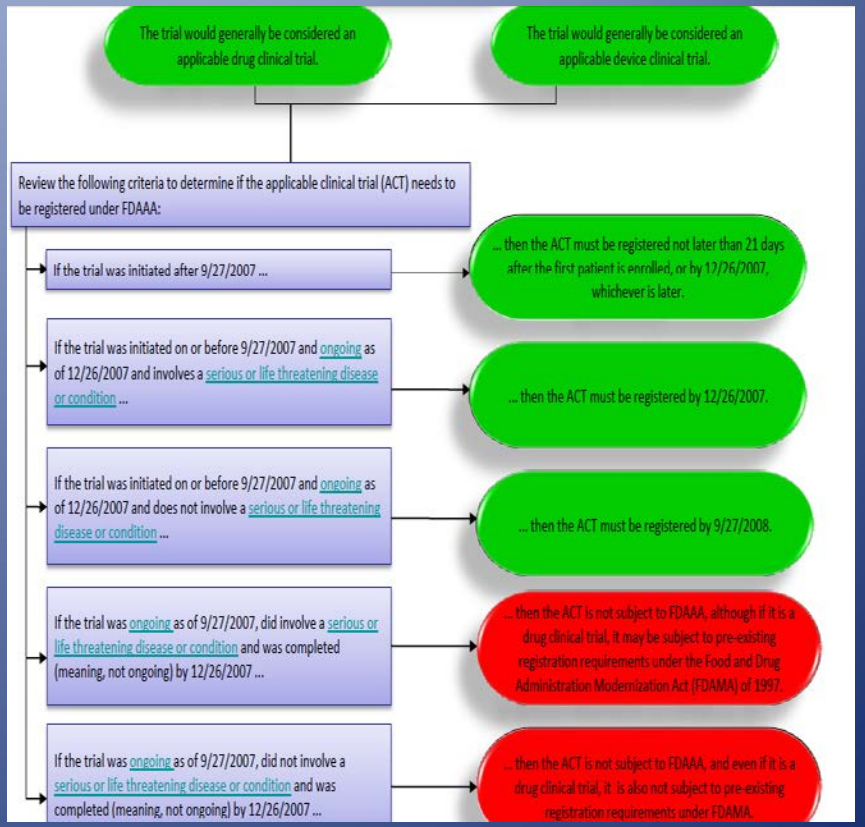
Clinical Trials.gov has developed the following algorythm which can be used to help determine if your project is an Applicable Clinical Trial. If your project meets **all** of the following criteria it **is generally** considered to be an applicable clinical trial:

- It is an intervention
- Intervention type is drug, biologic, device, radiation, or genetic
- It is currently in Phase 2, Phase 3 or Phase 4
- It is located in at least 1 location in the US OR is conducted under an Investigational New Drug/Investigational Device Exemption (considered to be FDA regulated)
- Recruitment status of IRB is not “withdrawn”.

Identifying an Applicable Clinical Trial

http://grants.nih.gov/ClinicalTrials_fdaaa/docs/Flow_chart-ACT_only.pdf





Example of an Applicable Clinical Trial

This study is currently recruiting participants.

Verified April 2013 by Virginia Commonwealth University

Sponsor:
Virginia Commonwealth University

Information provided by (Responsible Party):
Virginia Commonwealth University

ClinicalTrials.gov Identifier:
NCT01817751

First received: March 20, 2013
Last updated: April 23, 2013
Last verified: April 2013
History of Changes

Full Text View | **Tabular View** | **No Study Results Posted** | Disclaimer | How to Read a Study Record

Purpose

This phase II trial studies how well sorafenib tosylate, valproic acid, and sildenafil citrate works in treating patients with recurrent glioblastoma. Sorafenib tosylate, valproic acid, and sildenafil citrate may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth.

Condition	Intervention	Phase
Brain and Nervous System	Drug: sorafenib tosylate Drug: valproic acid Drug: sildenafil citrate	Phase 2

Study Type: Interventional
Study Design: Endpoint Classification: Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Phase II Study of Sorafenib, Valproic Acid, and Sildenafil in the Treatment of Recurrent Glioblastoma

Example of an Applicable Clinical Trial

This study is currently recruiting participants.

Verified May 2013 by Virginia Commonwealth University

Sponsor:
Virginia Commonwealth University

Information provided by (Responsible Party):
Virginia Commonwealth University

ClinicalTrials.gov Identifier:
NCT01836809

First received: April 17, 2013
Last updated: May 17, 2013
Last verified: May 2013
History of Changes

Full Text View | **Tabular View** | **No Study Results Posted** | Disclaimer | How to Read a Study Record

Purpose

The prevalence of renal dysfunction after implantation of the artificial heart is high. The infusion of exogenous B-type natriuretic peptide (BNP) after implantation of the total artificial heart (TAH) improves renal function in a sustained manner. The renal protective and hormone-modulating effects of nesiritide may be enhanced with ventriculectomy compared to heart failure surgery that leaves the native myocardium intact. The goal of this project is to determine the renal protective effects of nesiritide after implantation of a mechanical device.

Condition	Intervention	Phase
Congestive Heart Failure Cardiorenal Syndrome	Drug: nesiritide	Phase 4

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator)
Primary Purpose: Treatment

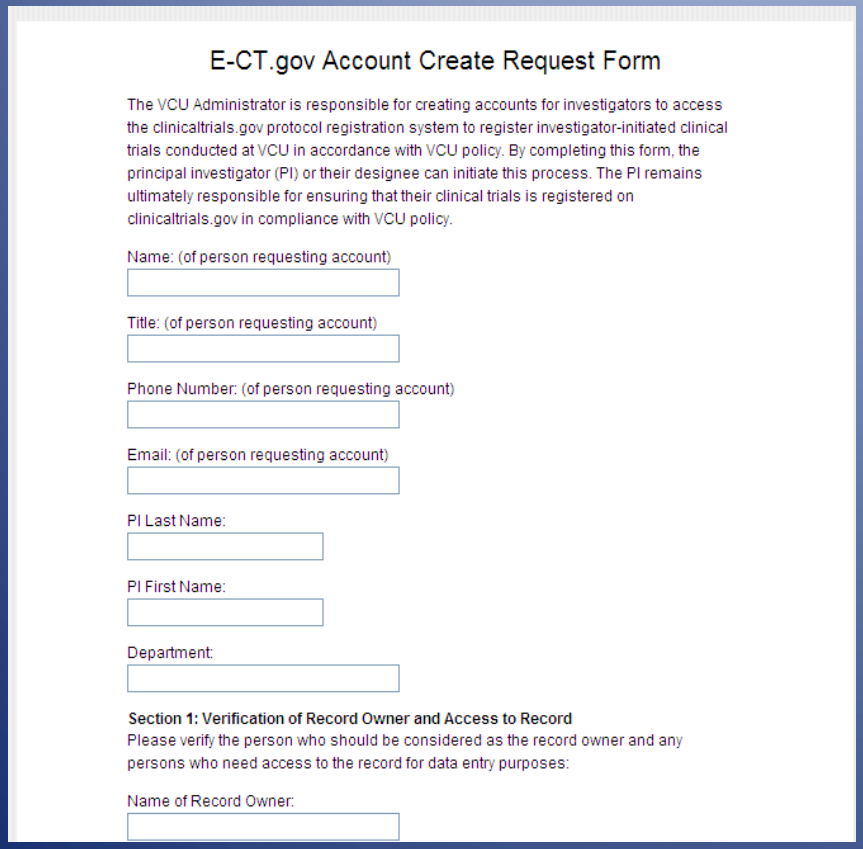
Official Title: The Impact of Nesiritide on Renal Function After Implantation of the Total Artificial Heart and Left Ventricular Assist Devices

Establishing a CT.gov Account

- VCU is responsible for ensuring the registration of Investigator-Initiated Clinical Trials.
- The Principal Investigator is responsible for ensuring the registration of his/her clinical trial prior to enrollment of the study subjects
- The Principal Investigator or his/her designee shall complete an electronic account create request form to establish an individual account. The individual submitting the request will be considered the record owner for any records created under this account. The request should include the individual's contact information as well as contact information for anyone who needs access to the protocol records. Once an account has been created, the record owner will receive an automated email reply containing a link to the registration site and login information.

http://www.research.vcu.edu/forms/e-ct_account_creation_form.htm

Establishing a CT.gov Account



E-CT.gov Account Create Request Form

The VCU Administrator is responsible for creating accounts for investigators to access the clinicaltrials.gov protocol registration system to register investigator-initiated clinical trials conducted at VCU in accordance with VCU policy. By completing this form, the principal investigator (PI) or their designee can initiate this process. The PI remains ultimately responsible for ensuring that their clinical trials is registered on clinicaltrials.gov in compliance with VCU policy.

Name: (of person requesting account)

Title: (of person requesting account)

Phone Number: (of person requesting account)

Email: (of person requesting account)

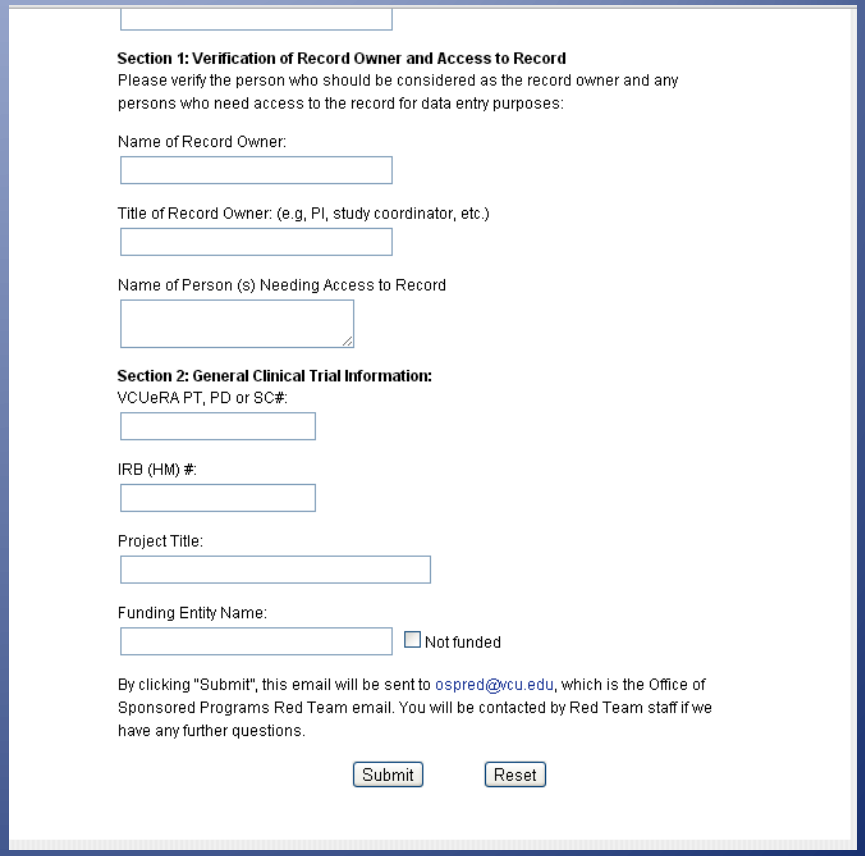
PI Last Name:

PI First Name:

Department:

Section 1: Verification of Record Owner and Access to Record
Please verify the person who should be considered as the record owner and any persons who need access to the record for data entry purposes:

Name of Record Owner:



Section 1: Verification of Record Owner and Access to Record
Please verify the person who should be considered as the record owner and any persons who need access to the record for data entry purposes:

Name of Record Owner:

Title of Record Owner: (e.g, PI, study coordinator, etc.)

Name of Person (s) Needing Access to Record

Section 2: General Clinical Trial Information:
VCUeRA PT, PD or SC#:

IRB (HM) #:

Project Title:

Funding Entity Name:

☐ Not funded

By clicking "Submit", this email will be sent to ospred@vcu.edu, which is the Office of Sponsored Programs Red Team email. You will be contacted by Red Team staff if we have any further questions.

Submit Reset

Why are there different registration requirements?

- VCU endorses registration of investigator-initiated clinical trials (regardless of funding) using the ICMJE definition to ensure protection of publication rights. Currently ICMJE includes Phase 1 studies in the definition and does not require results reporting.

- The law requires registration of a subset of clinical trials called “Applicable Clinical Trials” and those trials are required to have results reported in the Clinical Trials.gov protocol registration system no later than one year after the primary completion date (date of final collection of primary outcome measure).

- Mandatory language required in informed consent forms for Applicable Clinical Trials

- NIH requires certification of compliance with FDAAA on competing grant proposals and on non-competing progress report forms for grants where an Applicable Clinical Trial is supported in whole or in part.

Mandatory Informed Consent Form Language for Applicable Clinical Trials

- Per 21 CFR 50.25, As of March 7, 2012, the following mandatory language for applicable clinical trials has been required for informed consent documents:
- "A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

Requirement to Report on Grants from Federal Agencies

- **FDA Amendments Act (AKA PL110-85**)
-

- ‘‘(A) CLINICAL TRIALS SUPPORTED BY GRANTS FROM FEDERAL
- AGENCIES.—
- ‘‘(i) GRANTS FROM CERTAIN FEDERAL AGENCIES.—
- If an applicable clinical trial is funded in whole or
- in part by a grant from any agency of the Department
- of Health and Human Services, including the Food
- and Drug Administration, the National Institutes of
- Health, or the Agency for Healthcare Research and
- Quality, **any grant or progress report forms required**
- **under such grant shall include a certification that the**
- **responsible party has made all required submissions**
- to the Director of NIH under paragraphs (2) and (3).

Research Performance Progress Reports (RPPR)

- Non competing progress reports
- G.4.c includes CT.Gov Question: Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA? If yes, provide CT.gov identifier (8 digit number known as NCT #).
- http://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf
- http://grants.nih.gov/clinicaltrials_fdaaa/faq.htm#829

See What NIH Grantees Need to Know About FADAA , and FAQ When must an applicable clinical trial be registered? If the grant number was entered into ClinicalTrials.gov, the ClinicalTrials.gov identifier (NCT number) may be readily identified by using the ClinicalTrials.gov Advanced Search and entering the grant number in the *Study IDs* field.

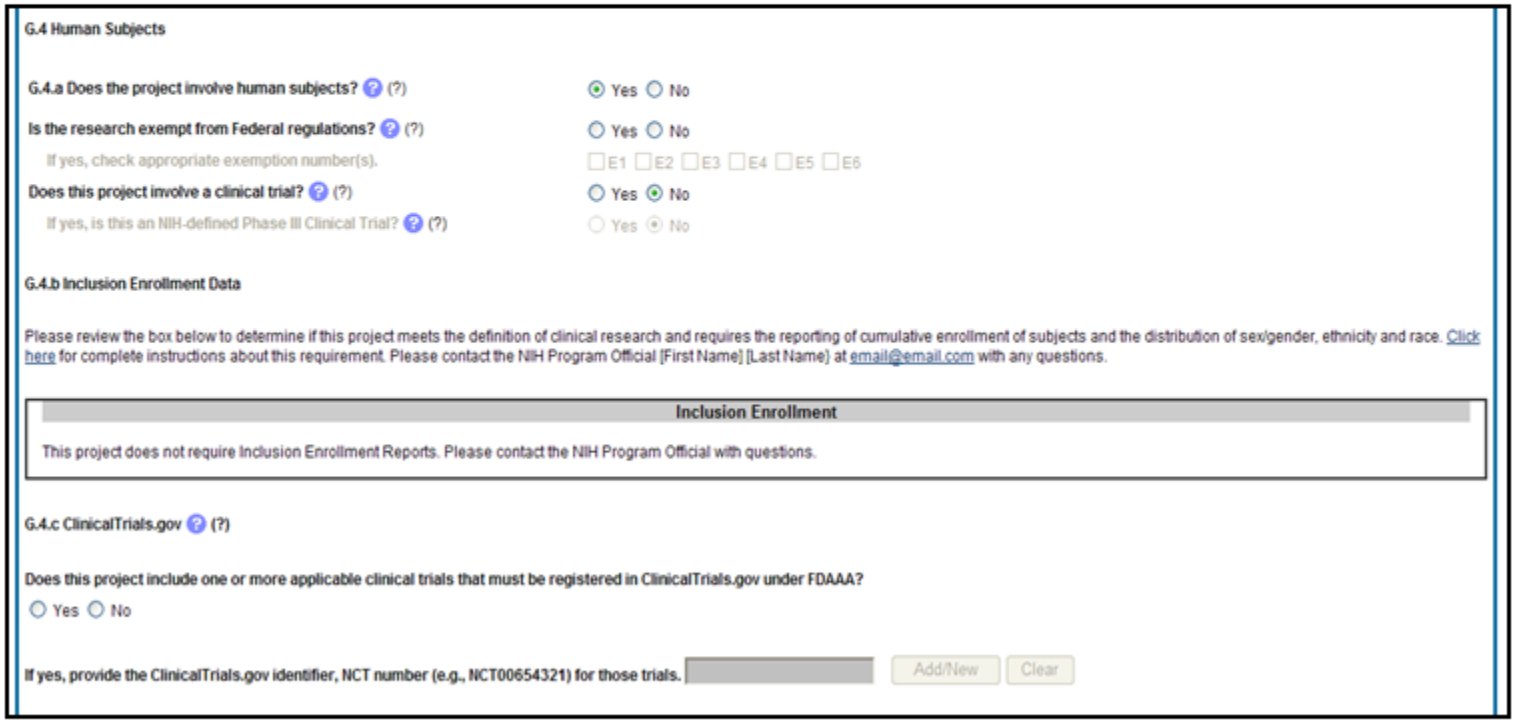


Figure 69: RPPR Section G. Special Reporting Requirements – Question G4

G.5 Human Subjects Education Requirement.

What's the Big Deal? What are the consequences of non compliance?

- Journals may deny your publication. May impact investigator's ability to obtain or retain funding. Jeopardizes VCU's ability to meet terms and conditions of award with the funding entity.
- **There is a potential penalty of up to $10,000 per day per study for non compliance with FDAAA.**
- May cause a disallowance of current federal funding or a withholding of future federal grant funding
- May impact reimbursement from Medicare. There are new requirements for reporting to Center for Medicare and Medicaid Services (CMMS)

CMMS Mandatory Reporting of NCT Number

- Effective January 1, 2014, it will be mandatory to report a clinical trial number on claims for items and services provided in clinical trials that are qualified for coverage as specified in the "Medicare National Coverage Determination (NCD) Manual," Section 310.1.

- http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8401.pdf

- http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R310OTN.pdf

- "The Centers for Medicare & Medicaid Services (CMS) uses this number to identify all items and services provided to beneficiaries during their participation in a clinical trial, clinical study, or registry. Furthermore, this identifier permits CMS to better track Medicare payments, ensure that the information gained from the research is used to inform coverage decisions, and make certain that the research focuses on issues of importance to the Medicare population "

Questions?

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