Welcome

Marcia Smith
Associate Vice Chancellor for Research
Agenda

- **Welcome and Announcements** – Marcia Smith
  - UC Patent Agreement Amendment

- **DGSOM Clinical Trials Contract Unit** – Helene Orescan
  - Coverage Analysis Process for Clinical Trial Budgets

- **RPC Update** – Ann Pollack
  - PHS COI Regulations

- **EFM Initiatives and Updates** – Tracey Robertson
  - Special Invoicing Requirements for CalTrans Funding

- **OARO Initiatives and Updates** – Jennifer Perkins
  - Funding Available from the “3 R’s” Program

- **OCGA Initiatives and Updates** – Patti Manheim
  - New Certification Requirement from NASA
  - UCLA Pilot of the Federal “Research Performance Progress Report” (RPPR) - Cindy Gilbert and Susan Waelder
Reminder!

- Acknowledge the UC Patent Agreement Amendment
Please fill out the survey forms
Coverage Analysis (CA)
Intro to CA at DGSOM at UCLA

Helene Orescan, J.D.
Bishoy Anastasi, MBA, CCRP
David Geffen School of Medicine at UCLA
Industry Sponsored Clinical Trials

March 8, 2012
What is Coverage Analysis?

Coverage Analysis documents the process of identifying procedural costs which may be billed to an insurer as “routine care” vs. research costs for procedures/services provided as a result of participation in a “qualified” clinical trial.

- **Routine Care (RC) – Billable to Insurer**
  - Provided to patients absent a clinical trial.
  - Required for administration of investigational item.
  - Necessary for subjects’ safety (clinical monitoring), or prevention of complication(s)
  - Medically necessary for diagnosis or treatment of complications arising from administration of investigational item.

- **Research Costs – Must be provided for by Sponsor or other Funding Source**
  - All other procedures/services
  - Must be provided by sponsor or another source of funding/support (NIH, Foundation, Grant, Internal Research Funds, etc.).
Routine Care Costs Do NOT Include:

- The Investigational Item or Service, unless otherwise covered absent the clinical trial.

- Items/services provided solely for data collection and research analysis (not used in the direct clinical management of subjects).
Coverage Analysis – What is a Qualifying Trial?

Must meet all of the following criteria to be considered a “qualifying trial”:

- Evaluates a Medicare benefit – item/service falls within a Medicare Benefit category and is not statutorily excluded from coverage (e.g. cosmetic surgery, hearing aids); and
- Has therapeutic intent – i.e. not designed exclusively to test toxicity/pathology; and
- Enrolls diagnosed beneficiaries – enroll patients with diagnosed disease rather than only healthy volunteers (but may also enroll a healthy control group); and
- Has desirable characteristics:
  - Trials funded by NIH, CDC, AHRQ, CMS, DOD and VA; or
  - Trials supported by centers or cooperative groups funded by same (above); or
  - Trials conducted under an IND reviewed by the FDA; or
  - IND exempt under 21 CFR 312.2(b)(1)
Why do we NEED to perform CA?!

Medicare

- September, 2000 – National Coverage Decision (NCD)
  - Provides coverage for Medicare beneficiaries participating in clinical trials for “usual” or “conventional care”

- 2005 – Rush Settles with Federal Government for $1 Million

- October, 2007 – Medicare Clinical Trials Policy (CTP)
  - NCD + clarifications
  - Provides expanded coverage for “qualified” clinical trials
  - Requires identification of all “billable” study procedures/services, regardless if “usual” or routine care.


UCOP

- 2010 UCOP Requires all UC medical centers to implement a system of Clinical Research Billing Compliance.
CA Eliminates Double-Dipping

Recent False Claims Settlements:

- Yale University $7.6M
- Mayo Clinic $6.5M
- Medical College of Georgia $6.1M
- Northwestern University $5.5M
- UCSD $4.7M
- Cornell University $4.3M
- Johns Hopkins $2.6M
CA Rollout at UCLA

- Study Feasibility Performed
- Budget Development (all protocol required procedures identified)
- Identify any “Routine Care” (RC) procedures/services.
  - If no RC, Coverage Analysis is not required. All procedures/services must be provided by sponsor or another funding source.
  - If RC identified, is this a “qualifying” clinical trial?
    - If not “qualifying”, all procedures/services must be provided by sponsor or another funding source.
    - If a “qualifying” CT, determine which RC costs are eligible for reimbursement from insurer.
Coverage Analysis Decision Tree

**Study Feasibility Performed**

> Budget Development (all procedures identified)

- Identify any RC procedures/services
  - If no RC, CA not required. All costs paid for by Sponsor or other funding source
  - If RC identified, is this a “qualifying” CT? (CTCU checklist in development)
    - If it is a “qualifying” CT, determine which RC costs are billable to insurer
## Visit Schedule – Budget – CA

<table>
<thead>
<tr>
<th>Procedure/Service</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
<th>EOT 360</th>
<th>Unscheduled Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Collection and prep for Central lab shipment (to include Hematology Profile, Chemistry Profile, Coagulation Profile and fasting Lipid Profile)</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Comprehensive Physical Examination (includes vitals)</td>
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<td>x</td>
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<td>x</td>
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<tr>
<td>Limited (focused) Physical Examination (w/o vitals)</td>
<td>x</td>
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<td>x</td>
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<tr>
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<tr>
<td>IV Infusion Therapy w/ 1 hr MD supervision</td>
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<td>x</td>
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<td>x</td>
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<tr>
<td>Percutaneous Renal Biopsy (hospital, technical and professional fees Neph &amp; Path)</td>
<td>x</td>
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<tr>
<td>Pneumococcal Vaccine</td>
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<td><strong>Local Labs:</strong></td>
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<tr>
<td>Urinalysis - automated w/ microscopy</td>
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<td>Blood Urea Nitrogen (BUN)</td>
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<tr>
<td>Tacrolimus trough level</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<td>Metabolic Panel (including Alkaline Phosphatase)</td>
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<td>x</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Pharmacy Dispensement Fee (oral study med)</td>
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<tr>
<td>Pharmacy Dispensement Fee (IV med)</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Procedure/Service</td>
<td>CPI/HCPCS</td>
<td>Unit Cost</td>
<td>Visit 1</td>
<td>Visit 2</td>
<td>Visit 3</td>
<td>Visit 4</td>
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<td>----------------------------------------------------------------------------------</td>
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<td>Pharmacy Dispensation Fee (IV med)</td>
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<td>Overhead (26%)</td>
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<tr>
<td>Total Dollar per Completed Patient</td>
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</tbody>
</table>

10
Documentation

• CTCU
  • Approves final CA and study budget.
  • Maintains final CA and study budget with contract file.

• Study Team (PI’s Responsibility)
  • Must document the CA process.
  • PI will certify CA and study budget.
  • Supporting CA documentation must be maintained with study records.
    • Study Teams should be prepared for an internal compliance audit.
Additional Resources

- UCLA Clinical Trials Website:
  - [http://clinicaltrials.ucla.edu](http://clinicaltrials.ucla.edu)
    Username: Password:
  - For Patient/Community
  - For Faculty/Staff
  - Contact us

Please note: Site access is limited to on-campus IT connections.
ClinicalTrials.ucla.edu

CLINICAL TRIALS AT UCLA

Participating in Clinical Trials

Latest News

- UCLA Stroke Researcher Honored by the American Heart Association
- Researchers uncover how new melanoma drug accelerates secondary skin...
- UCLA joins forces with White House to meet unique needs of veterans...
- Diet counts: Iron intake in teen years can impact brain in later life
- Young UCLA leukemia patient launches kid-friendly cookbook, hosts...

For Interested Research Participants

- Participating in Clinical Trials

Finding Clinical Trials at UCLA

- Cancer Trials at UCLA Jonsson Comprehensive Cancer Center
- Other Trials at UCLA

More News »
CTCU Distribution List

- CTCU Workshops
  - CT Budgets 101 – Intro to Industry CT Budget Development
  - CT Budgets 201 – Coverage Analysis
  - CT Budgets 301 – Advanced Budgeting (Investigator-Initiated)

- Email Updates, Upcoming Forums, etc.

- Contact: SEstrada@mednet.ucla.edu
Clinical Trials Contact Info

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Ann Pollack
Assistant Vice Chancellor – Research

March 8, 2012
Revised Public Health Service Regulations (Highlights)

• Intended to increase accountability, add transparency, enhance regulatory compliance and effective management of financial conflicts of interest and strengthen governmental compliance oversight
Revised Public Health Service Regulations (Highlights)

• Increases disclosure, review and reporting requirements
• Adds a education/training requirement
• Adds a new public accessibility requirement
• Adds new monitoring requirements
Conflicts of Interest in Research

- **Current federal regulations (PHS)** require that investigators disclose significant financial interests that would *reasonably appear to be affected by the research for which support is sought or in entities that would reasonably appear to be affected by that research.*
Conflicts of Interest in Research

- *Revised* PHS regulation requires that investigators disclose significant financial interests related to their *institutional responsibilities*
Significant Financial Interests under the revised PHS regulations

- Anything of monetary value related to the investigator’s institutional responsibilities including but not limited to:
  - **Salary or other payment** for services and the value of any equity in a publicly traded entity >$5,000
  - **Salary or other payment** for services >$5,000 or any equity in a privately held entity
  - **Intellectual property rights** (e.g., patents, copyrights and royalties not paid by UC) upon receipt of income related to such rights (of any $ value)
  - **Travel paid for, or reimbursed by, an outside entity** (of any $ value)
Institutional Responsibilities

- Draft UC definition

“For the purposes of this policy, the term institutional responsibilities is defined as teaching/education, research, outreach, clinical service, and University and public service, on behalf of UC[LA], and directly related to those credentials, expertise and achievements upon which the Investigator’s UCLA position is based.”
Examples of Activities related to Institutional Responsibilities

- **Income or honoraria** received for activities such as providing expert testimony or consulting services, serving on a board of directors, scientific advisory board, committee, panel or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies; acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a non-profit or for-profit organization, accepting a position as a salaried employee outside the University.

- **Stock or stock options** in a company developing, manufacturing or selling products or providing services used in an Investigator’s clinical practice, teaching, research, administrative or committee responsibilities;

- **Receipt of income from an organization other than The Regents** (such as royalties of licensing fees) for use or sale of patented or copyrighted intellectual property (e.g. software, textbooks, or other scholarly works); or

- **Travel** paid for or reimbursed by a professional society, a company for which the Investigator is consulting, or by any other for-profit or non-profit organization.
Review Process(es)

• *Revised* regulation require a two step review of activities related to an investigator’s institutional responsibilities to determine:
  
  1) if any disclosed significant financial interests would reasonably appear to be affected by the research for which support is sought or is in an entity whose financial interests would reasonably appear to be affected by that research, **and then**
  
  2) if any of those disclosed significant financial interests constitute a financial conflict of interest
Financial Conflict of Interest

“...a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.”

(Public Health Service regulations)
Revised Public Health Service Regulations: A Preview of Coming Attractions

• To be implemented by August 24, 2012
• Will be phased in with new PHS awards and new PHS proposals
• UC and UCLA drafting new policies and procedures specifically to address these regulations
• Just launched project to create an e-solution for disclosures.
Updates to Caltrans On-Call Agreement
Caltrans On-Call Agreement - Amendment

• Period of Agreement Extended:
  ▪ On-Call Agreement has been extended to 10/31/12
  ▪ AB20 Model Agreement should be implemented by the new end date
  ▪ If a Technical Agreement or Task Order (TA/TO) extends beyond 10/31/12 unexpended balances will need to be returned and a new award will be issued using the AB20 Model Agreement
Caltrans On-Call Agreement - Amendment

• Invoicing
  ▪ In addition to the Standard Detail Ledger Report we must also include a Detailed Payroll Expense Report
    ▪ Detailed Payroll Expense Report must include personnel paid and the time worked as a percent effort (or hours, if applicable to the position).
  ▪ PI is now required to endorse the invoice with the following statement:
    ▫ I have reviewed the expenditure detail for these accounts to determine the allowability of these charges to this project and certify that the salaries and wages included on these reports is an accurate representation of the actual time worked.
Caltrans On-Call Agreement - Amendment

• Invoicing
  ▪ The invoice package must then be sent by the PI to the Caltrans Program Manager for approval.
  ▪ EFM will insert the PI statement and a signature line for the PI on all Caltrans invoices.
  ▪ EFM will send the invoice package to Caltrans directly. However, Caltrans will not pay the invoice until the PI’s endorsed invoice package is received.
  ▪ EFM will continue to invoice Caltrans directly and send a copy to the PI for endorsement at the same time.
Caltrans On-Call Agreement - Amendment

• Invoicing
  - Caltrans will accept the PI signed Invoice Package by hard copy or email
  - PI Certification must be on the invoice itself, not in the body of an e-mail
  - Caltrans will accept a certified digital signature from the PI (such as one that can be generated via Adobe Acrobat)
  - PI should send a copy of the signed Invoice Package to EFM should there be future issues with questioned costs or difficulty in receiving payments
Today’s Topics

NASA Restriction on Funding Activities with the People’s Republic of China – Patti Manheim

NIH Research Performance Project Report (RPPR) – Susan Waelder, Cindy Gilbert
NASA Restriction with PRC

Grant Information Circular (GIC) 12-01 with Assurance of Compliance and Grant Award Provision - Ban on NASA funds used for collaboration with China, any company owned by the People’s Republic of China, or any Chinese-owned company (company incorporated under the laws of the PRC).
NASA Restriction with PRC

Applies to:
• Grants
• Cooperative Agreements
• ROSES 2012 Applications

Does NOT on its face restrict UC researchers who are Chinese from participating in research funded by the award.
NASA Restriction with PRC

OCGA Process:

- Review Scope of Work – Confirm no collaboration or making subaward to Chinese entity.
- Confirm with PI – in writing.
- Restriction in final email with fully executed award.
- Restriction on Synopsis:
  PIs are reminded that per UC policy, Chinese nationals cannot be discriminated against for participation in this project at UCLA. Additionally, PIs are still able to purchase commercial items of supply needed to perform the project from Chinese companies.
NASA Restriction with PRC

OCGA Process:

- Restriction on Synopsis:
  - Cannot participate, collaborate, or coordinate bilaterally in any way with China or any Chinese-owned company.
  - At any subrecipient level, whether the bilateral involvement is funded or performed under a no-exchange of funds arrangement.
  - PIs are reminded that per UC policy, Chinese nationals cannot be discriminated against for participation in this project at UCLA.
  - PIs are still able to purchase commercial items of supply needed to perform the project from Chinese companies.
“In some situations, the restrictions of the Acts may not apply to some Chinese national students, fellows, researchers, faculty, or principal and/or co-principal investigators participating under NASA grants and cooperative agreements provided the individual is not affiliated with the Chinese state to include the Government of the People's Republic of China or entities that are part of or controlled by the Chinese state. However, any situation that involves any participation by Chinese nationals will be reviewed on a case-by-case basis to determine whether restricted funds can be used under the circumstances.”
NASA Restriction with PRC – Troubling Language

- Suggests that there are cases in which the restrictions MAY apply to Chinese national researchers participating in the NASA awards, and that NASA will be seeking information regarding the nationality of people participating in awards in order to do a “case-by-case” assessment.

- That would be a problem with respect to UC’s policy/practice of not releasing individual citizenship information to sponsors.
NASA Restriction with PRC – Troubling Language

- UCOP is continuing review
- Raise to COGR
- Request Higher Education Association to approach NASA directly
RPPR Pilot

- Progress reports are required annually to document grantee accomplishments and compliance with terms of award. They describe scientific progress, identify significant changes, report on personnel, and describe plans for the subsequent budget period or year.
- The Office of Management and Budget (OMB) has mandated that federal agencies implement a federal-wide research performance progress report (RPPR) for submission of required annual or other interim performance reporting on grants and cooperative agreement awards to standardize recipient reporting on federally-funded research projects. NIH will implement the RPPR electronically through the eRA Commons.
RPPR Pilot

- OMB mandate for federal-wide Research Performance Progress Report (RPPR) to standardize reporting on federally-funded grants and cooperative agreements.
- Electronic submission using NIH eRA Commons.
- Partnering agencies will include FDA, CDC, AHRQ.
- UCLA is one of seven institutions involved in Pilot beginning in April 2012.
RPPR Pilot

- May be used for SNAP and fellowship reporting during initial phase of pilot.
  - Research project grants (R)
  - Institutional Training Grants (T)
  - Research career development awards (K)
  - Individual fellowship awards (F)
- May expand to other mechanisms Summer 2012.
RPPR Pilot

Timeline:
- Preliminary screenshots available now.
- Pilot system goes live April 20, 2012.
- Kick-off Webinar, hosted by NIH, April 26, 2012.
- Reports with due date of May 15, 2012 (July 1, 2012 start date).
- For May 15 reports OCGA will identify and contact potential participants.
- Details for June 15 and July 15 reports pending.
RPPR Pilot

Similarities to eSNAP:
• Report on progress, study results, significance of findings, and significant changes.
• Some information pre-populated from NIH systems.
• Publications in PD/PI’s MyNCBI displayed for easy association with progress report.
• Detailed budget *not* required.
• Compliance information required (human subjects education, inclusion enrollment, embryonic stem cells, etc.).
RPPR Pilot

Differences from eSNAP:
• Separate screens for reporting components:
  ▪ Cover Page
  ▪ Accomplishments
  ▪ Products
  ▪ Participants
  ▪ Impact
  ▪ Changes
  ▪ Special Reporting Requirements
RPPR Pilot

Differences from eSNAP:

• Information entered by
  ▪ Answering questions using checkboxes
  ▪ Text boxes
  ▪ PDF upload
  ▪ Selecting “Nothing to Report”.

• New information includes:
  ▪ Foreign component information
  ▪ Dollars (subawards) spent in foreign countries
  ▪ Organizational affiliation of personnel at foreign sights.
RPPR Pilot

Differences from eSNAP:

- Effort on All Personnel Report rounded to nearest (up or down) whole person month.
- Special location for reporting on competitive revisions/administrative supplements associated with the award.
- Public Access compliance displayed.
- Other support only required if there has been a change.
- Link to NOA in report.
RPPR Pilot

Advantages in participating:

• Familiarity with the system prior to full implementation.
• Interactivity provides immediate access:
  ▪ MyNCBI – publications
  ▪ eRA Commons - NOA
• Input regarding enhancements prior to full implementation.
• Clear text length recommendations based on guidance from NIH Program Officers.
Navigation bar at the bottom of each screen/section with “Save” button and hyperlinks to other sections/pages.
A. Cover Page

Grant Information

Grant Number: 5R01CA121626-03
Project Title: Cancer Research in Simple Note Abstracting Programs

[Regular, CDA & Ed] A.1 Program Director/Principal Investigator (PD/PI) Information
[F] A.1 Fellow Information

Name: Smith, John
E-mail: john.smith@university.edu
Phone: 123-456-7890
[F] Address: 123 Any Street, Your Town MD 21345

Is there a change of contact PD/PI on a multiple-PI award? ○ N/A ○ Yes ○ No
If yes, provide the eRA Commons ID of the new contact PD/PI
[Open List of Values (LOV)]

A.2 Submitting Official Information

Name: Brown, Jane
E-mail: jane.brown@university.edu
Phone: 123-456-7891

A.3 Administrative Official Information

Name: Brown, Jane
E-mail: jane.brown@university.edu
Phone: 123-456-7891

A.4 Recipient Organization Information

Organization Name: Outstanding University
Address: 123 Any Street, Your Town MD 21345
DUNS: 123456789
EIN: 1234567890A1

Project/Grant Period
Start Date: 10/01/2010
End Date: 09/30/2014

Reporting Period
Start Date: 10/01/2010
End Date: 09/30/2011

Requested Budget Period
Start Date: 10/01/2011
End Date: 09/30/2012

Report Frequency [Annual] [Other Frequency]
B. Accomplishments

B.1 What are the major goals of the project?

List the major goals of the project as stated in the approved application or as approved by the agency. If the application lists milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Generally, the goals will not change from one reporting period to the next. However, if the awarding agency approved changes to the goals during the reporting period, list the revised goals and objectives. Also explain any significant changes in approach or methods from the agency approved application or plan.

□ NIH "Goals" are equivalent to "specific aims." Significant changes in objectives and scope require prior approval of the agency (e.g., NIH Grants Policy Statement, 5.1.2).

List the major goals below (NIH recommended length is up to 1 page. Limit is 8000 characters or approximately 3 pages.)

□ (NIH) B.1.a Have the major goals changed since the initial competing award or previous report? □ Yes □ No

If yes, list the revised major goals below (NIH recommended length is up to 1 page. Limit is 8000 characters or approximately 3 pages.)

B.2 What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results, including major findings, developments, or conclusions (both positive and negative); and 4) key outcomes or other achievements. Include a discussion of stated goals not met. As the project progresses, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.
C. Products

☐ C.1 Publications

Enter My NCBI ()

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award? Yes / No

If yes, select from the table below to affiliate publications with this progress report. ()

<table>
<thead>
<tr>
<th>Associate with this RPPR</th>
<th>NIH Public Access Compliance</th>
<th>Citation</th>
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<tr>
<td>✓</td>
<td>Complete</td>
<td>Metlay JP, Observed association between antidepressant use and pneumonia risk was confounded by comorbidity</td>
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<tr>
<td>✓</td>
<td>In Progress</td>
<td>Hennessy S, Biker WB, Leonard CE, Chittams J, Palumbo CM, Karlwish JH, Yang YX, Lautenbach E, Baine WB, Metlay JP, Observed association between antidepressant use and pneumonia risk was confounded by comorbidity measures. J Clin Epidemiol., 2007 Sep; 60(9): 911-8; PMID:11689807; PMCID: PMC2042508</td>
</tr>
<tr>
<td>✓</td>
<td>Non-Compliant</td>
<td>Merriam NA, Putt ME, Metz DC, Yang YX, Hip fracture risk in patients with a diagnosis of pernicious anaemia. Gastroenterology, 2010 Apr; 138(4): 1330-7; PMID:20026065; PMCID: PMC2954457</td>
</tr>
</tbody>
</table>

Sort Table Above By

☐ Ascending  ☐ Descending

Then By

☐ Ascending  ☐ Descending

☐ (+) Show publications from My NCBI  ☐ (-) Hide publications from My NCBI  ☐ (?)
[Regular & CDA] (NIH) C.4 Inventions, patent applications, and/or licenses

[Regular & CDA] Have inventions, patent applications and/or licenses resulted from the award during this reporting period? ☐ Yes ☐ No

If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization? ☐ Yes ☐ No

Reporting of inventions through iEdison is strongly encouraged.

Mechanism-specific questions/instructions
D. Participants

[Regular, CDA & Ed] D.1 What individuals have worked on the project? [F] D.1 Not Applicable

[Regular, CDA & Ed] Provide or update the following information for: (1) program director(s)/principal investigator(s) (PDs/PIs); and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours or 6.3% of annualized effort).

Provide the name and identify the role the person played in the project. Indicate the nearest whole person month (Calendar, Academic, Summer) that the individual worked on the project. Show the most senior role in which the person has worked on the project for any significant length of time. For example, if an undergraduate student graduates, enters graduate school, and continues to work on the project, show that person as a graduate student.

☐ (NIH) NIH Instructions

- An individual’s Commons user ID may be used to partially populate his or her information.
- A Commons ID is required for all individuals with a postdoctoral role.
- Individuals with a postdoctoral-like role should be identified as “Postdoctoral (scholar)”. Do not include postdoctoral-like contributors who are not committing any significant effort to the individual’s project.
- Do not report personnel for whom a PHS 2271 Appointment form has been submitted.
- Required fields are marked with an *.

eRA Commons User ID ☐ (?)

 Populate from Profile

* First Name  Middle Name  Last Name

*Senior/Key Personnel? ☐  Last 4 digits of Social Security Number

☐ Yes  ☐ No

Supplement Support (SS) ☐ (?)

☐ Not Applicable

Degree(s)  *Project Role

Please Select a Role

Other (Project Role)

*Person Months ☐ (?)

☐ Calendar  ☐ Academic  ☐ Summer

DoB (MM/YYYY)
(NIH) G. Special Reporting Requirements

0.1 Special Notice of Award Terms and Funding Opportunity Announcement Reporting Requirements

Address any special reporting requirements specified in the award terms and conditions in the Notice of Award (NoA) or Funding Opportunity Announcement (FOA).

- Nothing to Report

or upload file(s)  Add Attachments

<table>
<thead>
<tr>
<th>Uploaded Files</th>
<th>Action</th>
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</tr>
<tr>
<td>File2.pdf</td>
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</tbody>
</table>


[CDA & F] Describe the responsible conduct of research instruction received (or instruction given as a course director, discussion leader, etc., in the case of senior fellows or senior career awardees) by formal and/or informal means, during this reporting period. If instruction or participation as a course director/discussion leader occurred in a prior budget period, note the dates of occurrence. Any activities undertaken to individualize instruction appropriate to career stage should be discussed. Address the five components: Format, Subject Matter, Faculty Participation, Duration, and Frequency. Additional detailed guidance on this requirement is found in the competing application instructions.

[Ed] If required in the FOA for this award, describe the nature of the responsible conduct of research instruction and the extent of participant and faculty involvement. Include a description of any enhancements and/or modifications to the five instructional components (Format, Subject Matter, Faculty Participation, Duration, and Frequency) from the plan described in the competing application. Faculty members who were contributors to formal instruction in responsible conduct of research during the last budget period must be named. Additional detailed guidance on this requirement is found in the competing application instructions.
QUESTIONS?