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 "qualifying" clinical trial.

- **Routine Care (RC) - Billable to Insurer**
  - Provided in 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)(3)
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”
- 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?
    - If RC identified, is this a “qualifying” CTU checklist in development
    - If it is a “qualifying” CT, determine which RC costs are billable to insurer
Visit Schedule – Budget – CA

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<th>Procedure/Visit</th>
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Office of Clinical Trials

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.
Clinical Trials Contact Info

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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

Questions?
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

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);

- **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.”

(INTERNATIONAL 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.
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

• 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 indicated 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.

NASA Restriction with PRC – Troubling Language

“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.

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.
QUESTIONS?