Diversifying Your Portfolio: Non-NIH Sources of Funding

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Training and career development awards for individuals with a research doctorate.

Sumandea C A, Balke C W Circulation 2009;119:1320-1327
Training and career development awards for individuals with a health professions doctorate.

Sumandea C A, Balke C W
Circulation 2009;119:1320-1327
Dorsey et al
JAMA, 2010

Funding source
- Medical device firms
- Biotechnology firms
- Pharmaceutical firms
- Private funds
- State and local government
- Federal support other than National Institutes of Health
- National Institutes of Health


Funding, US $ in Billions
- 0
- 20
- 40
- 60
- 80
- 100
- 120

% of total funding
- 33%
- 58%
Biomedical Research Funding

• In 2011, biomedical research funding reached $100 billion
• 65% Industry
  30% Government (NIH)
  5% Charities, Foundations, Donors
• Rate of increase in funding has decreased since 2003
• 4.5% of health spending is on biomedical research, only 0.3% is on health services, comparative effectiveness, new care models, best practices and quality/outcome/service innovations

Moses and Martin, NEJM 2011
Early Career Grant Programs

- CTSI Clinical Scholars Program
- Institutional Seed Grants
- Institutional KL2 career development awards e.g. CTSI and others
- Other K series mentored awards from NIH
- K90/R00 Pathway to Independence awards
What are the Extramural Research Opportunities?

**Major Sources:**

- Investigator Initiated Grants (RO1)
  - NIH – National Institutes of Health
  - NSF – National Science Foundation
  - ACS – American Cancer Society
  - AHA – American Heart Association

**Other Sources:**

- Program Project Grants (PO1, NIRT etc..)
- Other Government (DOD, DOE, DARPA…)
- Large Foundations (HHMI, Keck, etc…)
- Small Foundations
- Professional societies
- Industry
- Private donors
OCGA Website: http://www.research.ucla.edu/ocga/

Office of Contract & Grant Administration

Site Links
Note: You can also access these site areas via the menu above.
- Research Funding
- Proposal Preparation
- Forms & Templates
- Policies & Procedures
- Clinical Trials & Industry Research
- Conflicts of Interest in Research
- Electronic Research Administration
- Research Policy Index -- An alphabetical listing of UCLA, UC, and Federal links to research policies, procedures, and information

Important Updates
(Important Updates" section updated on 08/13/2004)

Principal Investigator Role and Responsibilities
On August 11, 2004, VC Peccei issued a memo reminding all research faculty and staff about the Principal Investigator's critical role and responsibilities for the design, conduct, and reporting of their research as well as supervision of employees, students, and postdoctoral fellows.

Click here to view the memo.

Acceptance of Incentive Payments, Gifts & Gratuities
On March 12, 2004, EVC Daniel Neuman issued a guidance memo reminding all employees of University policy regarding the acceptance of gifts and gratuities. See link below.

Click here to view the guidance memo.

NIH Salary Cap Q&A Update (06/25/2004)
The NIH Salary Cap Questions and Answers page has been updated.

Click here to view the new version.

Immigration Visa Processing
On October 30, 2003, VC Peccei issued a Deans, Directors, Department Heads, and Administrative Officers memo as guidance on the charging of immigration visa application fees, legal assistance fees, and visa processing recharges.

Click here to view the memo (PDF format)

August 2003 Memorandum from VC Roberto Peccei on Conflict of Interest in Research
On August 14, 2003, VC Roberto Peccei issued a memo in conjunction with the recent release of UCLA Policy and Procedures...
"How do I cite the CTSI grant number?"

Citations:
"The project described was supported by the National Center for Advancing Translational Sciences through UCLA CTSI Grant UL1TR000124."

Click here for more information

I'm a Researcher
Get information on CTSI resources and research assistance

I'm a Patient or Study Volunteer
Find out how CTSI supports community health and sign-up for a clinical trial near you.

I'm a Trainee
Access CTSI related course material using the Curriculum Tree.

ANNOUNCEMENTS & EVENTS
1. OCT 5TH Announcement Escalation With Overdose Control (EWOC) has a new Home at Cedars Sinai
2. OCT 8TH Announcement VIDEO: Dr. Antoni Ribas Discusses New Combination Therapy to Treat Metastatic Melanoma
3. OCT 10TH Announcement Drop-In Statistical Consulting: 12pm-1pm on Wednesdays

Research Facilities
CTSI investigators can access state-of-the-art laboratory and technology facilities. Find out about available resources.

Center for Translational Technologies >

Funding
Find out about available funding opportunities and get support writing your grant.

More >
for Trainees

View the Curriculum Tree

CTSI at UCLA offers a wide array of training courses and workshops in clinical and translational research as well as much needed mentoring support grants. Below is a summary of web pages that may be helpful to your educational pursuits.

- Research
  - Institutional Review Board
  - CTT Laboratory & Research Facilities
  - Research Tools
    - Social Networking and Collaboration Spaces Services
    - Research Data Repository
    - Clinical Trials Management System (CTMS)
    - Registry of Research Databases
    - caBIG Theory to Practice
  - Clinical Trials
- Education
  - Continuing Education
  - Training Program
    - Application Process
    - Track 2 Curriculum
      - Year 10 Curriculum, 2010-2011
      - BIOMATH 170A Introductory Biomathematics for Medical Investigators
      - BIOMATH 259 Controversies in Clinical Trials
      - BIOSTAT 100B Introduction to Biostatistics
Research Administration: Function

- Distribution of Funding Agencies Contacts and Funding opportunities
- Submission of grants and contract applications
- Provide pre-proposal consulting with investigators to ensure realistic budgeting, accuracy, and compliance with institutions
- Coordination with internal compliance committee.
- Set up awards internally, including communicating agency restrictions.
- Reconcile and close out projects and transmit progress and final reports to agencies.
- Confidentiality Agreements
- Material Transfer Agreements
- Contracts Negotiation……
Foundation Funding
Check websites and ask your Grants and Contracts office for Information

American Federation of Aging Research
American Heart Association
American Diabetes Association
California Endowment
California Wellness Foundation
Dermatology Foundation
Emergency Medicine Foundation
Juvenile Diabetes Foundation International
Lifeline Foundation, The
March of Dimes Birth Defects Foundation
National Kidney Foundation
Robert Wood Johnson Foundation
Susan G. Komen Breast Cancer Foundation ………
American Heart Association

Programs Funded by American Heart Association Early Career Awards (Research in CV Disease/stroke)

Pre-doctoral (Students)
- Post-doctoral (Trainee career development)
- Beginning Grant-In-Aid (Promising beginning scientists)
- Scientist Development Grant (Highly promising scientists, progress to independence)

- Fellow-to-Faculty Transition Award (Trainees to Physician-Scientist)
- National Clinical Research Program (Early Career Investigators with mentors, pilot grants)
- National Scientist Development Grant (Beginning scientists, progress to independence)
Other Funding Mechanisms for Junior Investigators (PhDs/MDs)

- California Breast Cancer Research Program – IDEAS for new investigators, post-doc, <3 years as independent investigator, $100-150K

- Tobacco Related Disease Research Program – Exploratory and Developmental Research: preliminary data/proof of concept ($125K x 2 y) Research Project: fully developed projects (150K x 3y)

- American Diabetes Association – Junior Faculty Award (new investigators) $120K x 3y Career Development Award (Asst. Prof) $150K x 5y
Foundation Grants

• Go to the web-site and check out the details
• Discuss your application with your mentor and the grants and contracts office
• Ensure the aims of the study fits the goals of the foundation and will provide meaningful outcome
• Start preparation for the application early
• Obtain external review when possible
• Each foundation has different application deadlines and formats
• Some may not use the “just in time” mechanisms for IRB and other regulatory approvals.
Industry Supported Grants

– Investigators initiated, industry supported grants (investigator develops hypothesis, aims and design of study, applies to industry for a grant to conduct the study)

– Industry initiated, industry sponsored studies (single or multi-center clinical trials, industry designs and monitors study, investigators participates as sites for the clinical trial)
Industry Supported Studies

Investigators initiated, industry supported studies

- Similar to grant application to foundations
- Hypothesis, Aims, Study Design, Biostatistics developed by investigators
- Usually involves marketed product or those in development by the industry sponsor
- Conduct of the study under good clinical practice (ICH guidelines) are the investigators’ responsibility
- Industry may request review of results before publication
Industry Supported Studies

Industry initiated, industry sponsored studies (Phase 2, 3)

– Study designed and originated by sponsor
– Only minor changes to protocol sometimes possible
– Investigator and site selected by sponsor
– Monitoring of study conducted by sponsor to meet FDA and Fed Regulations
– Data analysis done by sponsor’s biostatistician
– Study report written by investigator/scientific writer
Industry Supported Studies
Industry initiated, industry sponsored studies

- Read the protocol carefully
- Ensure the protocol is scientifically interesting
- Assess adequate participants required by the study
- Contact CTSI “facilitator”
- Contact the grants and contracts office early to initiate contract negotiations
- Contact grants and contracts for assistance in developing budgets
Industry Supported Studies

Industry initiated, industry sponsored studies

- Budgets based on per subject
- Discuss with your clinical trials expert
- Develop a budget to cover your time and effort and also that of your team
- Never under budget
- Your team should be able to meet or exceed the commitment for recruitment for any study
# Industry Sponsored Study Budgets

<table>
<thead>
<tr>
<th>Procedures</th>
<th>Unit Cost</th>
<th>Screening</th>
<th>Treatment Period 1</th>
<th>Treatment Period 2</th>
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<td><strong>Up to 30 Days</strong></td>
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<td>Report to Study Center</td>
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<td>$ 15</td>
<td>$ 15</td>
<td>$ 15</td>
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<tr>
<td>Confinement at study centre / PK unit</td>
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<tr>
<td>Informed Consent</td>
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<td>Demography</td>
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<tr>
<td>Medical History</td>
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<td>Concomitant Medications</td>
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<td>$ 25</td>
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<td>$ 25</td>
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<td>Physical Examination</td>
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<td>ECG</td>
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<td>Vital Signs</td>
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<td>Laboratory Handling Fee</td>
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<td>$ 25</td>
<td>$ 25</td>
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<td>Pharmacokinetic Blood Sample Collection</td>
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<td>$ 50</td>
<td>$ 100</td>
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<td>Randomisation</td>
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<td>Patient Training 1</td>
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<td>Study Drug Administration 2, 3</td>
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<td>Complete Daily Dosing Chart 2, 3</td>
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<td>Baseline Signs and Symptoms</td>
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<tr>
<td>Recording of Adverse Events</td>
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<tr>
<td>Draize Assessment</td>
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<td>$ 50</td>
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<tr>
<td>Subject Inconvenience Cost</td>
<td>$ 75</td>
<td>$ 100</td>
<td>$ 75</td>
<td>$ 150</td>
</tr>
</tbody>
</table>

Notes:
1. ** = Day 2, *** = Day 3
2. 2, 3, and 5 refer to different treatment periods.
3. PK unit denotes pharmacokinetic unit.
4. Demography includes basic demographic data.
5. Pharmacokinetic Blood Sample Collection includes blood samples for pharmacokinetic analysis.
6. Vital Signs includes routine vital sign monitoring.
7. Laboratory Handling Fee includes administrative costs associated with laboratory testing.
8. Concomitant Medications include any additional medications taken during the study.
9. Physical Examination includes a comprehensive physical examination.
10. ECG refers to electrocardiogram testing.
11. Randomisation involves the process of allocating study participants to treatment groups.
12. Patient Training includes any educational or instructional sessions for study participants.
13. Study Drug Administration involves the administration of study drugs.
14. Complete Daily Dosing Chart includes daily records of drug administration.
15. Baseline Signs and Symptoms includes recording of initial signs and symptoms before treatment.
16. Recording of Adverse Events includes monitoring and record-keeping of adverse events.
17. Draize Assessment involves toxicological assessments.
18. Subject Inconvenience Cost includes costs related to any inconvenience experienced by the subject during the study.
Industry Supported Studies
Industry initiated, industry sponsored studies

– Recruitment and retention of study participants crucial to the success of your participation in clinical trials
– Experience, enthusiasm, and commitment of the study team (coordinators) critical
– Learn Good Clinical Practice
– Review inclusion and exclusion criteria very carefully
– Obtain IRB and other regulatory approvals early (external IRB?)
– Start recruitment and aim at recruiting more and faster than any other participating sites
Industry Supported Grants

Industry initiated, industry sponsored grants

– Attend and actively participate at the investigators’ meetings
– Express concerns and make suggestions to improve the protocol
– Identify the key personnel and your contacts for the proposed study
– Meet with your study team frequently to resolve issues
– Review all AEs and sign all reports and forms within a short period of time e.g. 2 to 3 days
– Meet with study monitor at each visit, debrief with team after monitor’s visit
Industry Supported Grants
Industry initiated, industry sponsored grants

- Usually sponsor selects a Principal Investigator for the study (experienced researcher in the field)
- Be the PI if possible
- Discuss authorship of publications early
- Authorship on publication frequently depends on the number of subjects your site has enrolled
- Volunteer to write or review manuscript if possible
Industry Sponsored Studies

- Gain experience in design and conduct of clinical trials
- Develop team of support personnel for conduct clinical and translational research
- Play a role in drug development to improve health and treat diseases
- Contribute to scientific literature on therapeutics
Example of Successful Industry Academic Collaboration

- Sponsor contact our group to develop a transdermal androgen
- Protocol developed jointly by investigators and sponsor and approved by FDA
- Multicenter clinical trials initiated with our group as PI
- Study completed, study report reviewed by our group
- NDA application submitted by sponsor and approved
- New transdermal gels available as new delivery system of androgens
- New products accepted by many hypogonadal men
- Lead site for many other androgen replacement studies
- Investigators elected to be on National and International guidelines committees
Example of Successful Industry Academic Collaboration

Publications:


Other Studies

Buccal, Transdermal, Oral Androgens


