Diversifying Your Portfolio: Non-NIH Sources of Funding

Christina Wang, MD
Associate Director, UCLA-CTSI
Los Angeles Biomedical Research Institute
Harbor-UCLA Medical Center
Professor of Medicine
David Geffen School of Medicine at UCLA

Intramural 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 awards

What are the Extramural Research Opportunities?

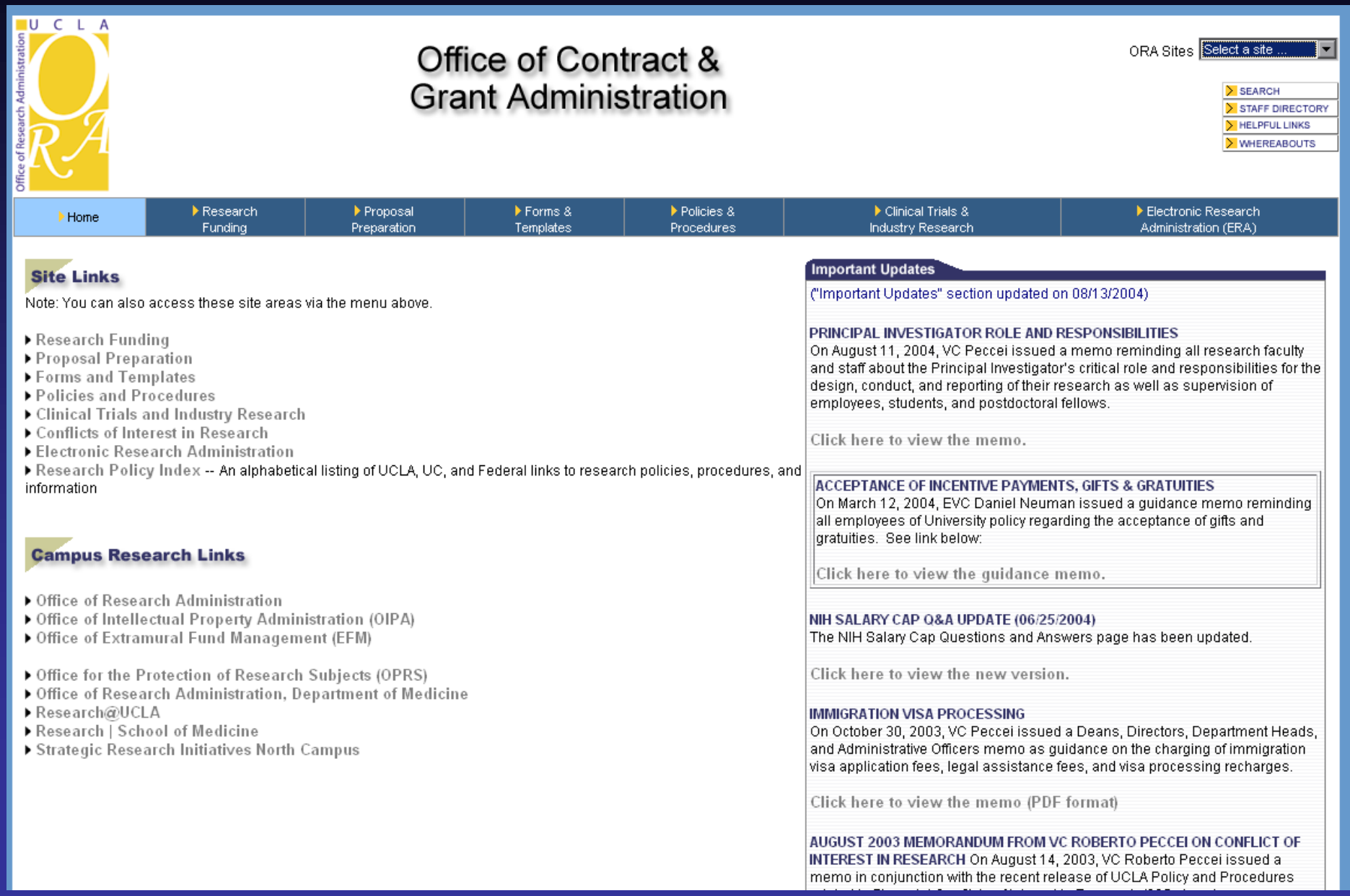
Major Sources:

- 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
- Industry
- Private donors

OCGA Website: http://www.research.ucla.edu/ocga/



LA BioMed
Los Angeles Biomedical Research Institute
at Harbor-UCLA Medical Center

Research Administration

- 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 with 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 (http://www.americanheart.org)

- Pre-doctoral
- Post-doctoral
- Fellow-to-Faculty Transition Award
- Beginning Grant-In-Aid
- Established Investigator Award (suspended)

- National Clinical Research Program (Early Career Investigators)
- National Scientist Development Award (Beginning scientist

American Heart Association

Fellow-to-Faculty Transition Award

Provides funding for trainees with outstanding potential for careers as physician-scientists in cardiovascular or stroke research during the crucial career development from the completion of research training through the early years of the first faculty/staff position. Physicians who hold an M.D., D.O., M.D./PhD. (not Ph.D.) or equivalent doctoral degree are eligible.

American Heart Association

National Clinical Research Award

- Encourages early career investigators who have appropriate and supportive mentoring relationships to engage in high quality introductory and pilot clinical studies.

American Heart Association

National Scientist Development Grant

Supports highly promising beginning scientists in their progress toward independence by encouraging and adequately funding research projects that can bridge the gap between completion of research training and readiness for successful competition as an independent investigator.

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 x2 y) Research Project: fully developed projects (150K x 3y)
- American Diabetes Association – Junior Faculty Award (new investigators) $120K x3y
  Career Development Award (Asst. Prof) $150K x5y

Foundation Grants

- Go to the web-site and check out the details
- Discuss your application with 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

- 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

Procedures	Unit Cost	Screening	Treatment Period 1				Treatment Period 2
		Up to 30 Days	Day 1	Days 2 - 5	Day 6	Day 7	Day 8
Report to Study Center	$ 15	$ 15	$ 15		$ 15	$ 15	
Confinement at study centre / PK unit [4]	$ 700					$ 700	$ 700
Informed Consent	$ 75	$ 75					
Demography	$ 25	$ 25					
Medical History	$ 100	$ 100					
Concomitant Medications	$ 25	$ 25	$ 25		$ 25	$ 25	$ 25
Physical Examination	$ 150	$ 150					
ECG	$ 91	$ 91					
Vital Signs	$ 15	$ 15	$ 15		$ 15	$ 15	$ 15
Laboratory Handling Fee	$ 25	$ 25	$ 25		$ 25	$ 25	$ 25
Pharmacokinetic Blood Sample Collection [5]	$ 50	$ 50	**$ 100**		$ 50	**$ 350**	$ 50
Randomisation	$ 50		$ 50				
Patient Training [1]	$ 25		$ 25				$ 25
Study Drug Administration [2, 3]	$ 25		$ 25	**	***	***	$ 25
Complete Daily Dosing Chart [2, 3]	$ 25		$ 25	**	***	***	$ 25
Baseline Signs and Symptoms	$ 25	$ 25					
Recording of Adverse Events	$ 25		$ 25		$ 25	$ 25	$ 25
Draize Assessment	$ 50		$ 50		$ 50	$ 50	$ 50
Subject Inconvenience Cost		$ 75	$ 100		$ 75	$ 150	$ 100

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 and enthusiasm of the study coordinators critical
- Learn Good Clinical Practice
- Review inclusion and exclusion criteria very carefully
- Obtain IRB and other regulatory approvals early
- 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 resolved 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 be 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 approvedNew 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:

Wang C, Berman N, Longstreth JA, Chuapoco B, Hull L, Steiner B, Faulkner S, Dudley RE, Swerdloff RS. Pharmacokinetics of transdermal testosterone gel in hypogonadal men: application of gel at one site versus four sites: A General Clinical Research Center Study. J Clin Endocrinol Metab 85:864-969, 2000.

Wang C, Swerdloff RS , Iranmanesh A, Dobs A, Snyder PJ, Cunningham G, Matsumoto AM, Weber T, Berman N, and the Testosterone Gel Study Group. Transdermal testosterone gel improves sexual function, mood, muscle strength, and body composition parameters in hypogonadal men. J Clin Endocrinol Metab 85:2839-2853, 2000.

Swerdloff RS , Wang C, Cunningham G, Dobs A, Iranmanesh A, Matsumoto AM, Snyder PJ, Weber T, Longstreth J, Berman N, and the Testosterone Gel Study Group. Long Term Pharmacokinetics of Transdermal Testosterone Gel in Hypogonadal Men. J Clin Endocrinol Metab 85:4500-4510, 2000

Wang C, Swerdloff RS, Iranmanesh A, Dobs A, Snyder PJ, Cunningham G, Matsumoto AM, Weber T, Berman N and the Testosterone Gel Study Group. Effects of transdermal testosterone gel on bone turnover markers and bone mineral density in hypogonadal men. Clin Endocrinol 54:739-750, 2001

Wang C, Cunningham G, Dobs A, Iranmanesh A, Matsumoto AM, Snyder PJ, Weber T, Berman N, Hull L, and Swerdloff RS. Long-Term Testosterone Gel (AndroGel) Treatment for Maintains Beneficial Effects on Sexual Function and Mood, Lean and Fat Mass, and Bone Mineral Density in Hypogonadal Men. J Clin Endocrinol Metab 89:2085-2098, 2004.

Other Studies

Buccal, Transdermal, Oral Androgens

- Wang C, Swerdloff RS, Kipnes M, Matsumoto AM, Dobs AS, Cunningham G, Katznelson L, Weber TJ, Friedman TC, Snyder P, and Levine HL. New Testosterone Buccal System (Striant) Delivers Physiologic Testosterone Levels: Pharmacokinetics Study in Hypogonadal Men. J Clin Endocrinol Metab 89:3821-3829, 2004.
- Wang C, Harnett M, Dobs A, Swerdloff RS. Pharmacokinetics and Safety of Long-Acting Testosterone Undecanoate Injections in Hypogonadal Men: An 84-Week Phase III Clinical Trial. J Androl 31:457-65, 2010
- Wang C, Ilani N, Arver S, McLachlan R, Soulis T, Watkinson A. Efficacy and safety of the 2% formulation of testosterone topical solution applied to the axillae in androgen-deficient men. Clin Endocrinol 2011
- Yin AY, Htun M, Swerdloff RS, Diaz-Arjonilla M, Dudley RE, Faulkner S, Bross R, Leung A, Baravarian S, Hull L, Longstreth JA, Kulback S, Flippo G, Wang C. Re-Examination of Pharmacokinetics of Oral Testosterone Undecanoate in Hypogonadal Men with a New Self-Emulsifying Formulation. J Androl. 2011 Apr 7. [Epub ahead of print]