Research at Stanford
An overview for new faculty
05/03/17

Harry Greenberg, MD
Senior Associate Dean for Research
Spectrum Director
Current State of Stanford SOM Research

- Research Funding and Demographic Data
- Research Service Centers
- Support for Clinical and Translational Research
- Financial Support Services
- Grant Preparation Services
- Conflict of Interest Services and Policies
Stanford University: FY 2016 Sponsored Projects Research

**Proposals and Awards**

<table>
<thead>
<tr>
<th>Category</th>
<th>Proposals</th>
<th>Awards</th>
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<tbody>
<tr>
<td>Medicine</td>
<td>77%</td>
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<tr>
<td>Engineering</td>
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<tr>
<td>Humanities &amp; Sciences</td>
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<td>Dean of Research</td>
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<td>Education</td>
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<tr>
<td>Earth, Energy &amp; Env. Sciences</td>
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<td>Business</td>
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<td>Law</td>
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**Expenditures**

<table>
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<tr>
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<tr>
<td>Business</td>
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**Notes**

- Proposals and awards exclude industry-sponsored clinical trials (except for awards-count), fellowships, and the following agreements: collaboration, data/facilities use, personnel, and university research.
- Expenditures include sponsored research contracts and grants (total directs and reimbursed indirect expenditures).
- Department of Bioengineering proposals and awards totals are split between the School of Medicine and the School of Engineering.
- Dean of Research includes faculty PIs from the schools who are working in Stanford's independent labs/centers/institutes.
Stanford University SoM: NIH Funding

**STANFORD UNIVERSITY NIH RANKING FOR MEDICAL SCHOOLS**

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**NIH FUNDING TOP 5 MEDICAL SCHOOLS (IN 2015)**

- UCSF
- Johns Hopkins
- Stanford
- Penn
- Wash U
Stanford University SoM: All Research

**PROPOSALS TOTAL DOLLARS (BILLIONS)**

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<tr>
<th>Year</th>
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**NEW AWARDS TOTAL DOLLARS (MILLIONS)**

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Legend:
- Non-Fed (excl CIRM)
- CIRM
- Fed (excl NIH)
- NIH: ARRA
- NIH (excl ARRA)
Basic data on clinical and translational research (CTR)

Number of Stanford Faculty Conducting CTR

All Clinical Research

<table>
<thead>
<tr>
<th>Year</th>
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Clinical Trials

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Excludes the Department of Bioengineering.
CTR Research Focus Areas (FY 2015) at Stanford

All Clinical Research

- Cancer: 35%
- Child Health: 16%
- Genetics: 14%
- Neuroscience - Psychiatry: 14%
- Chronic Disease: 12%
- Cardiovascular: 12%
- Immunology - Transplantation Medicine: 11%
- Population Science - Epidemiology: 5%
- Aging: 5%
- Stem Cell - Regenerative Medicine: 4%
- Microbiology - Infectious Disease: 4%
- Cell Biology - Biochemistry - Dev Biology: 3%
- Global Health: 3%
- AIDS: 2%

* An active award can have multiple research focus areas. Excludes BioE and 7% of awards with no designated research focus.
Scientific Service Centers
Shared facilities open to all Stanford researchers that operate by cost-recovery
http://corefacilities.stanford.edu

• Imaging (various types)
  – microscopes: confocal, TIRF, array tomography, luminescence, in vivo 2P confocal, super-resolution, SEM, TEM
  – luminescence and fluorescence small animal imaging
  – MRI: human (3T and PET-MRI) and small animal (7T)
  – small animal PET and SPECT with CT, Momentum Magnetic Particle Imaging (1st commercial instrument in the world)
  – small animal ultrasound and photo-acoustic imaging
  – histology (both human and animal)

• Omics
  – nucleic acid library prep (including single cell), sequencing (nextgen, Sanger, and pyro), and data analysis, microarrays, oligo synthesis
  – proteomics/mass spectrometry, metabolomics, peptide synthesis, protein production, nano-immunoassay, SPR interaction analysis (Biacore)
Scientific Service Centers (2)

- **Translational**
  - characterization of human immune status using FACS, CyTOF, cytokine immunoassays, and by measuring gene expression (sequencing, microarrays, qPCR)
  - tissue bank (being organized—see Spectrum slides)
  - screening of small molecule and siRNA libraries, drug formulation, drug pharmacokinetics (*in vitro* and *in vivo*)
  - analysis of clinical datasets (including database design and statistical analysis)

- **Animal models**
  - veterinary services
  - transgenic and knockout mice, tumor models
  - neuroscience behavioral models
  - AAV (and other viruses) expressing optogenetic channels and other proteins of interest to neuroscience researchers
Scientific Service Centers (3)

- Other Stuff
- Flow cytometry including FACS and CyTOF
- Drosophila melanogaster food and stocks
- Shared licenses for commonly used scientific software
- 3D printing

For more information: [http://corefacilities.stanford.edu](http://corefacilities.stanford.edu) or contact Bruce Koch (bkoch@stanford.edu)
What is Spectrum?

A University Independent Center Supporting Clinical and Translational Research (CTR)

Education → Trainees and mentors

Innovation → Innovation Accelerators and Seed grant funding

Implementation → Selected Resources and Services

Funding: NIH Clinical & Translational Science Award (2008-2018)
School of Medicine Office of the Dean
Office of the Vice Provost and Dean of Research
Child Health Research Institute

spectrum.stanford.edu
Spectrum Education

- Trainee and scholar support: 6 new per year
  - Mentored Career Development (K12)
  - Research Training (TL1)
  - Postdoctoral Fellows

- MS Epi & CR / HSR
- Biodesign & CERC

- One-week intensive course in clinical research
- Online courses
- Mentoring
- Principles & practices of early-phase translational research
- Research staff education and training
Spectrum Innovation Accelerator

- **Spectrum Innovation Award Grants**
  - Five areas of funding $15K-$50K/yr
    - Biodesign (Medical Devices)
    - SPARK (Therapeutics)
    - SPADA (Predictives and Diagnostics)
    - Population Health Sciences
    - Learning Healthcare Innovation Challenge

- **Child Health Pilot Award Program**
  - Four types of support $35K/yr
    - Early career
    - New idea
    - Bridge funding
    - Postdoctoral salary support
What is Spectrum?

Education → Trainees and mentors

Innovation → Seed grant funding

CTR Implementation → Service and Resources
Direct Services
Consultations

- **Biostatistics***
  - Statistical design, sample size, power calculations (QSU)
  - Study Design Workshop

- **Informatics***
  - Secure database setup and data management
  - STRIDE: Cohort identification, research alerts
  - DASHER

- **Ethics**
  - Research-related issues that raise ethical concerns

*The Statistical and informatic support services currently being merged, expanded and reorganized into a single unit (DASHER)*
Freidenrich Center Direct Services
Clinical and Translational Research Unit

- Outpatient clinical research space
- Nursing support
- Phlebotomy and **Biospecimen processing and banking**
- Research sample processing
- 2nd and 3rd floors support cancer center clinical operations
Direct Services
Regulatory Support

Office of Clinical Research Quality

- IND/IDE support
- CT.gov support
- Investigator and coordinator training
- Audit preparation and support
  clinicalresearchquality@stanford.edu
RMG’s Services for Faculty
(Research management Group)

• Funding Opportunity Announcements
• Pre-Award: Proposal preparation and submission
• Post-Award: Award acceptance/management
• Industry-Sponsored Clinical Trials
• Reporting and Analytics (for leadership)

http://med.stanford.edu/rmg
RMG’s Services: Funding Opportunities

• Funding opportunities for all federal agencies, foundations, and industry sponsors
  – Email announcements to faculty *(from Jeanne Heschele)*
  – Funding Opportunities website: http://med.stanford.edu/rmg/funding
RMG’s Services: Proposals & Awards

• All proposals and awards for externally sponsored projects **must** be processed through RMG.

• Contact your assigned Research Process Manager (RPM) for assistance and guidance
Policy on PI Eligibility and Criteria for Exceptions

• Eligibility to act as a principal investigator (PI) or co-principal investigator (Co-PI) on externally sponsored projects is a privilege limited (by the academic council) to members of the Academic Council (UTL and NTL-Research appointments) and to MCL faculty

• For CEs, a PI waiver need to be obtained
  – http://med.stanford.edu/rmg/piwaiver.html
The RMG Clinical Trial Contract team includes Clinical Trial Research Process Managers (CTRPM) and Clinical Trial Contract Officers who provide budgeting and contracting services. (lean process in place to speed budgeting and contracting)

http://med.stanford.edu/rmg/clinical_trial.html
Priority Areas:

1. Assist with large (>\$1M direct costs per year), complex, multi-investigator grant applications such as program project or center grants, e.g., NIH P01, P50, and U54 grant applications.

2. Assist with applications related to Dean’s and University initiatives, e.g., precision health (PMI) and big data.

3. Assist junior faculty writing their first major research project grants, e.g., NIH R01 grants.
Examples of Services Provided by SRDO

• Identify funding opportunities (with Jeanne Heschele); liaise with funding agencies
• Create proposal submission timeline
• Suggest additional team members to fill gaps in expertise
• Proposal development and advice on grantsmanship
• Edit, revise, and format text and figures; meet page limits
• Analyze proposal critiques
• Provide examples of administrative sections (e.g., facilities, human subjects research, etc.)
• Collect letters of support, biosketches, etc.
• Coordinate with RMG, OSR, Dean’s Office, etc.
SRDO Contact Information

- Michael K. Helms, PhD, MBA
  - Director of SRDO
  - Modular B, Room 41
  - mkhelms@stanford.edu

- Sandra R. Holden, PhD
  - Grant Development Officer
  - Modular B, Room 51
  - srholden@stanford.edu

- The earlier you contact our office, the more assistance we can provide. Services are based on availability and alignment with priority areas.
What Faculty Can and Can’t Do Under Stanford Research Conflict of Interest (COI) Policies
The Point of COI Disclosure

• “A conflict of interest occurs when there is a divergence between an individual's private interests and their professional obligations to the University such that an independent observer might reasonably question whether the individual's professional actions are determined by considerations of personal gain, financial or otherwise. A conflict of interest depends on the situation, and not on the character or actions of the individual.”
Can Do

• Consult up to 13 days/quarter
  – Includes roles like member of Advisory Board (AB) or Board of Directors (BOD)
  – Providing scientific, medical, and/or medical/legal advice
  – Giving educational talks/training
    • Where the faculty member controls the topic, content, and materials
Can’t Do

- Serve in a line management role at a company
- Serve as a PI outside of Stanford
- Faculty cannot receive research funding from his/her start up company (SBIR/STTR grants at Phase I excepted)
- Serve on a ‘Speakers Bureau’ or other ‘marketing’ activities
Human Subjects Research and the Rebuttable Prohibition

- Stanford follows the ‘rebuttable prohibition’, that is an investigator with a financial interest >$10,000 in income, equity in a publicly traded company (or combination of the two), or any equity in a privately held company, is considered too conflicted to conduct the research unless he/she has a compelling justification for an exception to this prohibition.
COI Resources

• DoResearch website:
  – [https://doresearch.stanford.edu/research-scholarship/conflicts-interest](https://doresearch.stanford.edu/research-scholarship/conflicts-interest)

• Contact the Conflict of Interest Review Program:
  – Barbara Flynn at [bflynn@stanford.edu](mailto:bflynn@stanford.edu) or 723-7226
  – Shannon Shankle at [sds@stanford.edu](mailto:sds@stanford.edu) or 723-0969