Welcome

Marcia Smith
Associate Vice Chancellor for Research
• Welcome and Announcements - Marcia Smith

• EFM – Yoon Lee
  ▪ Single Audit Update

• RSAWA
  ▪ Institutional Biosafety Committee (IBC) – Alyse DiStefano

• OCGA – Patti Manheim
  ▪ CA State Agencies F&A and LA County Contracts Timesheets – Jim Fong
  ▪ OCGA Master Training: NIH Assist Basics from the Preparers Perspective, March 21st from 9:30 AM – 11:00 AM – Kathy Kawamura
ORA Announcements

Contract and grant funds that were awarded with new UCLA F&A rates will be adjusted at the start of FY2019

- Federal research and public service awards that included new rates will be modified in FS to apply the rates that are effective FY2019
ORA Announcements

UCOP has expanded restrictions on F&A exceptions for State- and federally-funded agreements

- Exceptions require multiple levels of approval and are not guaranteed
- Apply full rates if exception has not been approved in advance
- More info from Jim Fong on today’s agenda
ORA Announcements

New financial system implementation project to begin soon

- Significant role for research administration

- More at April 2018 RAF
RESEARCH ADMINISTRATION

Extramural Fund Management
March 8, 2018
Today’s Topics

- Single Audit for FY16-17
Audits

UC receives two audits every year by independent auditors besides numerous audits by sponsoring agencies.

Financial Statement Audit
- Independent, objective evaluation of financial reports and financial reporting processes to obtain reasonable assurance that financial statements are free from material misstatement.
- In accordance with Generally Accepted Accounting Principles (GAAP) and standards established by Governmental Accounting Standards Board (GASB).

Single Audit (2 CFR 200. 501 Audit Requirements)
- Independent examination of an entity that expends $750,000 or more of federal assistance to ensure that appropriate internal controls over compliance are in place and that federal funds are spent in compliance with the federal program's requirements.
PwC completed the audits for the University of California for the fiscal year ended June 30, 2017 (FY16-17).

- Preliminary work started in April 2017
- Fieldwork were performed in June and September 2017
- Testing of all selected transactions was completed in February 2018

Campuses selected for full-scope testing for single audit were:

<table>
<thead>
<tr>
<th>Research &amp; Development</th>
<th>UCLA, UCSD</th>
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<tbody>
<tr>
<td>Student Financial Assistance</td>
<td>UCB, UCSD, UCR</td>
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</table>

The University’s audit report for FY16-17 was submitted to the federal government on March 1, 2018 through Federal Audit Clearinghouse (FAC).

A copy of full report is available at the UCOP and FAC websites.

http://www.ucop.edu/financial-accounting/financial-reports/a-133-audit-reports.html
https://harvester.census.gov/facdissem/SearchA133.aspx
### Single Audit Testing

- Extensive number of samples selected for testing: total 561.
- Comprehensive documentation required.

<table>
<thead>
<tr>
<th>Central Office</th>
<th>Compliance Requirements (# of samples selected)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFM</td>
<td>A/B: Allowable Activities/ Costs (154)</td>
</tr>
<tr>
<td></td>
<td>C: Cash Management (75)</td>
</tr>
<tr>
<td></td>
<td>G: Matching (10)</td>
</tr>
<tr>
<td></td>
<td>H: Period of Performance (75)</td>
</tr>
<tr>
<td></td>
<td>L: Reporting (25)</td>
</tr>
<tr>
<td></td>
<td>N: Special provision: Salary Cap (25)</td>
</tr>
<tr>
<td>OCGA</td>
<td>M: Sub-recipient monitoring (80)</td>
</tr>
<tr>
<td></td>
<td>N: Special provisions: Key personnel (42)</td>
</tr>
<tr>
<td>CFS</td>
<td>F: Equipment and Real Property (50)</td>
</tr>
<tr>
<td></td>
<td>I: Procurement (25)</td>
</tr>
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</table>
As part of the Single Audit, the auditor prepares three following reports.

- The first report provides auditor’s opinion on whether the University’s financial statements are presented in accordance with US Generally Accepted Accounting Principles (GAAP).

- The second report describes the scope of auditor’s testing of internal controls and compliance and the results of testing in accordance with Generally Accepted Government Auditing Standards (GAGAS).

- The third report provides auditor’s opinion on compliance with requirements that could have a direct and material effect on each of the selected major federal programs on internal control over compliance in accordance with UG.

- Audit results including auditor’s opinion are summarized in “Schedule of Findings and Questioned Costs” in the report.
Definitions

- **A deficiency in internal control exists when:**
  - The design or operation of a control over compliance does not allow management or employees, in the normal course of performing their assigned functions, to prevent, or detect and correct noncompliance on a timely basis.

- **Significant deficiency:**
  - A deficiency, or a combination of deficiencies, in internal control over compliance that is less severe than a material weakness in internal control, yet important enough to merit attention by those charged with governance.

- **Material weakness:**
  - A deficiency, or combination of deficiencies, in internal control over compliance, such that there is a reasonable possibility that material noncompliance with a type of compliance requirement of a federal program will not be prevented, or detected and corrected on a timely basis.
# UC: Summary of Auditor’s Results

## Financial Statements

<table>
<thead>
<tr>
<th>Type of auditor’s report</th>
<th>Unmodified (clean opinion) “UC Financial statements are presented fairly, in all material respects, in accordance with Generally Accepted Accounting Principles (GAAP)”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal control over financial reporting</td>
<td>Material weakness identified?</td>
</tr>
<tr>
<td></td>
<td>Significant deficiencies identified?</td>
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<tr>
<td></td>
<td>Noncompliance material to the financial statement?</td>
</tr>
</tbody>
</table>

## Federal Awards (Single Audit)

<table>
<thead>
<tr>
<th>Type of auditor’s report issued on compliance for major programs</th>
<th>Unmodified (clean opinion) “UC compiled, in all material respects, with the types of compliance requirements in accordance with Uniform Guidance”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal control over major program</td>
<td>Material weakness identified?</td>
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<tr>
<td></td>
<td>Significant deficiencies identified?</td>
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<tr>
<td></td>
<td>Noncompliance material to the financial statement?</td>
</tr>
<tr>
<td>Audit findings required to be reported in accordance with 2 CFR 200.516(a)?</td>
<td>Yes</td>
</tr>
</tbody>
</table>
R&D Federal Award Findings

- UCLA and UCOP did not have any reportable findings.
- 8 federal award findings were reported.
- 4 following findings were related to R&D:
  - Equipment additions and inventory
    - Testing disclosed an instance where equipment was capitalized at a wrong amount.
  - Cash management timing of reimbursement requests
    - Prior year finding: Testing disclosed instances where LOC cash drawdown reimbursements included expenses posted to the g/l but not paid.
    - Corrective action has been implemented but was not in place during the FY16-17.
  - Key personnel monitoring
    - Prior year finding: Testing disclosed instances where evidence of having obtained appropriate approvals for key personnel changes was not in place.
    - Corrective action has been taken but not fully implemented during the FY16-17.
  - Service Centers
    - Testing disclosed instances where evidence of having performed a rate review could not be obtained.
# Areas for Closer Monitoring

<table>
<thead>
<tr>
<th>Areas</th>
<th>Key Reminders</th>
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</table>
| A/B: Allowable Activities/ Costs | Adequate answers to questions for all cost transfers  
Timely cost transfers (late cost transfers should be rare and require extensive explanation)  
Documentation of appropriate approvals on purchase of goods and services  
Travel: PI’s approval / evidence that travelers worked on the project |
| G: Matching                  | Complete cost sharing contribution report with supporting documents as needed to verify the amount |
| H: Period of Performance (POP) | Timely recording of expenses in the general ledger (g/l)  
Documentation of expenses posted in the g/l outside POP  
Timely and complete closeout packet  
PI’s certification on the closeout packet |
| L: Reporting                 | Reconciling expenses per g/l to the final invoice or financial report.  
Cleaning up g/l: transfer off unallowable expenses timely. |
| N: Special Provision: Key personnel | Monitor actual effort to ensure committed effort is satisfied  
Report actual effort correctly in the progress report and effort reports.  
Obtain sponsor’s approval for a 25% reduction or more to committed effort |
Single Audit for FY17-18

- PwC will conduct audits for UC for FY17-18.
- Campuses for full scope testing have not been determined yet but to be determined in April 2018.
- Preliminary fieldwork is scheduled to begin in May 2018.
Contact information

EFM Website
http://ora.research.ucla.edu/EFM/

Yoon Lee
X40375
yoon.lee@research.ucla.edu
The Institutional Biosafety Committee

Presented by:
Alyse DiStefano, IBC Manager
March 8, 2018
RSAWA Compliance Committees

ORA Research Safety and Animal Welfare Administration

IBC  RSCs  CPSC  DURE  OSOC  ARC
Office of the Vice Chancellor for Research
IBC Member Appointments

Office of Research Administration (ORA)

IBC Administrative Office
- All administrative support for the IBC
- Regulatory compliance issues
- Incident and non-compliance reporting to NIH
- Annual reporting to NIH
- Policies
- Education and outreach on IBC issues

Office of the Vice Chancellor of Administration

Environment, Health & Safety (EH&S)

EH&S Biosafety Program
- Expertise on biosafety issues
- Incident Investigation
- Biosafety inspections and training
- Facility design consultations
- Emergency response
- Medical Waste Management Program
- Select Agent and Toxin Program
- BSL3 Program
- Primary contact for regulatory agencies
The Institutional Biosafety Committee (IBC)

- Mandated by the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.
- Faculty-led committee appointed by the Vice Chancellor for Research.
- Reviews **Biological Use Authorization (BUA)** applications.
- Experts in various fields including plant containment, animal containment, clinical trials, infectious disease, field research.
Scope of UCLA’s IBC

Academic research and teaching operations using the following materials:

- Recombinant and synthetic nucleic acid molecules
- Infectious agents
- Select Agents and Select Toxins
- Human and nonhuman primate materials
- Genetically-modified animals and whole plants
- Animals known to be reservoirs/vectors of zoonotic diseases
IBC Risk Assessment Process

The IBC considers the following items when performing a biological risk assessment:

- PI Expertise
- Proposed Biosafety Level
- Proposed Locations
- Engineering Controls (e.g., biosafety cabinet, aerosol-tight devices)
- Biosafety Practices
- Risk of Environmental Release
- Standard Operating Procedures (SOPs)
- Personnel Training (e.g., EH&S, lab-specific)
- Hazard Communication
- Occupational Health Considerations (e.g., vaccinations, medical surveillance)
Standard Conditions of Approval

✔ Completion of Training by All Personnel
   Visit [https://Worksafe.ucla.edu](https://Worksafe.ucla.edu) to sign up for in-person trainings or to complete online trainings.

✔ Satisfactory EH&S Biosafety Review (Inspection)
   • Review of procedures/operations
   • Review of facilities
   • Review of biosafety manual

✔ Ancillary Approvals (ARC, IRB, ESCRO, etc.)
4.1.12 Health and Safety Regulations and Guidelines

Recipients are responsible for meeting applicable Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to NIH grants. In addition to applicable Federal, State, and local laws and regulations, the following regulations must be followed when developing and implementing health and safety operating procedures and practices for both personnel and facilities:


Recipient organizations are not required to submit documented assurance of their compliance with or implementation of these regulations and guidelines. However, if requested by the awarding IC, recipients should be able to provide evidence that applicable Federal, State, and local health and safety standards have been considered and have been put into practice.
NIH Grants Policy Statement

4.1.26 Research Involving Recombinant or Synthetic Nucleic Acid Molecules (including Human Gene Transfer Research)

4.1.26.1 Scope and Availability

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) (April 2016 or latest revision) apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an organization that receives NIH support for recombinant or synthetic nucleic acid molecule research. A copy of the NIH Guidelines is available at http://osp.od.nih.gov/office-biotechnology-activities/biosafety.nih-guidelines

According to the NIH Guidelines, recombinant and synthetic nucleic acid molecules are defined as (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2). The NIH Guidelines apply to both basic and clinical research studies. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the NIH Guidelines.

Failure to comply with these requirements may result in suspension or termination of an award for recombinant or synthetic nucleic acid molecule research at the organization, or a requirement for NIH prior approval of any or all recombinant or synthetic nucleic acid molecule projects at the organization. Two specific requirements of the NIH Guidelines are discussed below, but the recipient should carefully review the NIH Guidelines in their entirety to ensure compliance with all of the requirements for projects involving recombinant or synthetic nucleic acid molecules.

Recombinant or synthetic nucleic acid research involving select agents also is subject to pertinent CDC and USDA regulations, 42 CFR 73, Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121, Possession, Use, and Transfer of Biological Agents and Toxins.
4.1.24.1 Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents)

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C. 201, is designed to provide protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the U.S. homeland or other criminal acts. The Act was implemented, in part, through regulations published by HHS and USDA at 42 CFR 73, 9 CFR 121 and 7 CFR 331 or commonly referred to as "Select Agent Regulations." Copies of these regulations are available at http://www.selectagents.gov/Regulations.html, or can be obtained from CDC, 1600 Clifton Road, MS A-46, Atlanta, GA 30333; telephone: 404-718-2000.

4.1.24.1.1 Select Agents
4.1.24.1.1.1 Select Agent Awards to U.S. Institutions

Domestic recipients who conduct research involving select agents or toxins (see Section 3 and 4 of 42 CFR 73 and 9 CFR 121 and Section 3 of 7 CFR 331) must maintain a registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving select agents or toxins if the registration certificate maintained by CDC or USDA is suspended or revoked.
<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does this proposal involve the use of significant IT resources (beyond basic academic infrastructure); the generation of datasets or digital assets; or a budget with over $10,000 in IT-related hardware, software, or staff expenditures? (Check additional requirements)</td>
<td>False</td>
</tr>
<tr>
<td>Human Subjects? If yes, indicate &quot;Pending&quot;, IRB # or Exemption #:</td>
<td>False</td>
</tr>
<tr>
<td>NIH-funded Clinical Trial? If yes, investigators and staff involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice. Training is available through CITI Program. Provide names on the next page.</td>
<td>False</td>
</tr>
<tr>
<td>Will the clinical research study utilize UCLA Health System resources, including but not limited to, any patient care costs? If yes, then a Policy 915 Coverage Analysis is required (contact <a href="mailto:coverageanalysis@mednet.ucla.edu">coverageanalysis@mednet.ucla.edu</a>).</td>
<td>False</td>
</tr>
<tr>
<td>Animal Subjects? If yes, indicate &quot;Pending&quot; or ARC#:</td>
<td>False</td>
</tr>
<tr>
<td>Human Embryonic Stem Cell Research? If yes, refer to the Stem Cell Policy and Procedures.</td>
<td>False</td>
</tr>
<tr>
<td>Non-UCLA materials/equipment to be used? If yes, indicate type:</td>
<td>False</td>
</tr>
<tr>
<td>Human or primate cells, tissue, or fluids; recombinant or synthetic nucleic acids; potentially infectious materials; exotic plants or plant pathogens; select agents or toxins? For more information, see IBC website.</td>
<td>True</td>
</tr>
<tr>
<td>Use of UC IP? If yes, specify case number:</td>
<td>False</td>
</tr>
</tbody>
</table>
Welcome to IBC

**Bookmark:** Bookmark the above URL for easy access. In your browser, go to
Favorites → Add To Favorites or Bookmarks → Bookmark This Page

**Logon:** When prompted, log in using your UCLA Logon ID (formerly Bruin Online account). If you have forgotten your logon ID or need to reset your password, visit [http://logon.ucla.edu](http://logon.ucla.edu)

**IBC Help Desk**
Phone Number: 310-794-0262
Hours: 8am – 5pm, Monday – Friday
dibc@research.ucla.edu
The UCLA Institutional Biosafety Plan

https://ucla.app.box.com/v/UCLA-Biosafety-Plan
Contact Information

ibc@research.ucla.edu
310-794-0262
http://ora.research.ucla.edu/RSAWA/IBC
State of California - Recent History

• January 2010 – Assembly Bill 20 directed the State of California to negotiate model contract terms for UC and CSU for research, training or public service projects
• November 2015 – All three parties signed an MOU to implement the California Model Agreement (CMA) starting January 1, 2016.
• Negotiations did not address Patents and Indirect Costs (IDC)
The CA IDC Plan 2016

<table>
<thead>
<tr>
<th>Facilities</th>
<th>Administration</th>
<th>Total Rate</th>
<th>Base</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>25%</td>
<td>25%</td>
<td>MTDC</td>
<td>January 1, 2016</td>
</tr>
<tr>
<td>5%</td>
<td>25%</td>
<td>30%</td>
<td>MTDC</td>
<td>July 1, 2017</td>
</tr>
<tr>
<td>10%</td>
<td>25%</td>
<td>35%</td>
<td>MTDC</td>
<td>July 1, 2018</td>
</tr>
<tr>
<td>15%</td>
<td>25%</td>
<td>40%</td>
<td>MTDC</td>
<td>July 1, 2019</td>
</tr>
</tbody>
</table>
### The CA IDC Plan 2018

<table>
<thead>
<tr>
<th>Facilities</th>
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<td>25%</td>
<td>40%</td>
<td>MTDC</td>
<td>July 1, 2021</td>
</tr>
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Standing Exceptions

The authority to approve indirect cost exceptions for Federal and State of California agencies rests with the UC Office of the President (UCOP)

• California Department of Food and Agriculture (CFDA)
  ▪ 15% through June 30, 2018, 20% through June 30, 2019, and 25% through June 30, 2020

• Marketing Orders, Agreements, Councils and Commissions
  ▪ various

• California Institute for Regenerative Medicine (CIRM)
  ▪ complicated formula and not a straight percentage
Requesting an Exception

- An exception request requires Chancellor or designee approval
  - A clearly stated rationale for the reduced indirect cost recovery
  - What differentiates the project from other projects to merit exceptional treatment
  - The mere fact that the solicitation limits indirect costs is not enough reason for UCOP to approve
- Exception requests are sent to UCOP Chief Financial Officer for consideration
Individual Exceptions

- Office of Statewide Health Planning and Development (OSHPD)
- California Department of Transportation (Caltrans)
Case Study (Caltrans)

Caltrans – Division of Research, Innovation, and System Information (DRISI)

- August 2017 – formal proposal submitted using the 25% IDC rate for $200,000
- December 2017 – Caltrans program official tells PI to submit a budget at 20% IDC rate based upon DRISI Directive 17-009
  - IDC would lower from $40,000 to $33,333
Case Study (Caltrans)

• Lots and lots of phone calls with the PI!!!
• Discussions involving Marcia Smith, VCR, PI’s Dean and Chancellor Block
• January 10, 2018 – Caltrans IDC issue is discussed at the Council of Chancellors who all agreed to hold firm at the 25% IDC rate
  ▪ “This action is a necessary step toward UC’s recovery of a greater portion of the full, real costs of research, which are needed in order for UC to maintain the operations of its first class campuses”
Case Study (Caltrans)

- February 1, 2018 – compromise is reached between Caltrans DRISI and UCOP
  - Some allowed at 20% with the rest at 25%
- Further negotiation between Caltrans and UC/CSU on an appropriate IDC rate
  - Stay tuned
Proposal Reminder

- New State of California IDC Rates should be used when the project:
  - 30% - starts between July 1, 2019 and June 30, 2020
  - 35% - starts between July 1, 2020 and June 30, 2021
  - 40% - starts after July 1, 2021

- IDC rate will be locked for the "life of the project"
Proposal Tips

• What to do when a solicitation limits Indirect Costs to a lower rate than what UCOP allows?
  ▪ Inform and advise the PI that UCOP needs to approve an exception to policy and UCLA may not be able to accept the award
  ▪ If PI wants to move forward with the proposal at the lower rate outlined in the solicitation, provide OCGA a rationale as outlined earlier for the Chancellor’s consideration
  ▪ OCGA will also need to contact the Sponsor to discuss the use of UC/CSU’s standard rate for State of California
Los Angeles County – Recent Issue

• Several projects funded by the Ryan White HIV/AIDS Program
  ▪ Federally funded program through the LA County
  ▪ Program provides medical care and essential support services for people living with HIV who are uninsured or underinsured
Required Timesheets

- LA County interpreted a certain provision to require UCLA to track the number of hours worked each day for all employees paid on the project.

- “Employee time and effort to be documented, with charges for the salaries and wages of hourly employees to … be supported by records indicating the total number of hours worked each day”
Required Timesheets

- UCLA cannot do this for its exempt employees who function in a “bona fide executive, administrative, or professional capacity”
  - 29 CFR Part 516.3 excludes such individuals from reporting time in the number of hours each workday
- UCLA’s Effort Reporting System (ERS) is used to keep track of effort by percentage on federally funded projects
- ERS is an accepted system and methodology that reflects the distribution of covered employees’ activity allocable to each project
Timesheets Resolution

• Several group discussions and face-to-face meetings between UCLA and LA County
• Breakthrough this week: LA County accepted the ERS

• Things left to do:
  ▪ Work on contract language to prevent this issue from happening again
  ▪ Work with other LA County Departments on a model Contract Agreement
Proposal Tips

• For proposal budgets requesting hourly rates
  ▪ Don’t do it!
  ▪ If compelled to provide this information, include a disclaimer in the Budget and Budget Justification
Hourly Rate Disclaimer

- **Disclaimer**: The individuals included in this proposal are appointed to Full Time Effort (FTE) positions and appointments on externally sponsored projects are a percentage of that full time effort. The University of California does not pay these employees based on labor hours but rather by percent effort. Budgetary figures based on hours and or hourly rates are inconsistent with the University’s practices and are provided for estimating purposes only. Furthermore, the University will not bill by hours but rather by percent effort. The University’s effort reporting and invoicing are consistent with the percent of effort process outlined in OMB Circular A-21 Cost Principles for Educational Institutions, Section J.10.c.
This session will provide a preparer’s perspective on how to utilize NIH’s proprietary proposal submission system (ASSIST) for Multi-Project Applications (MPA). It is suggested that attendees acquaint themselves with the NIH Application Guidelines for MPAs, along with the FOA prior to class. This session will address basic functions of the system along with hints and tips for the department preparers and PIs to employ, ensuring an on-time compliant (error-free) application.
MASTER TRAINING

http://www.research.ucla.edu/ocga/training-calendar.html

APRIL
Outgoing Subaward Basics

MAY
NSF Fastlane / Research.gov