What are the goals?

- understand that research at UM (and elsewhere) is complicated
- obtain a framework for navigation of regulations and requirements for research
- obtain a reference list of people/offices who are here to help
University of Miami and Miller School Research Infrastructure

• provides specialized facilities, research infrastructure, and a safe environment
• assists in identifying and obtaining extramural funds
• manages relationships between researchers and funding entities
• provides oversight of regulatory aspects, including human subject protection, conflict of interest management, and animal welfare protection

Uresearch.miami.edu
University of Miami Research Leadership

John L. Bixby, Ph.D.,
Vice Provost for Research

Dushyantha Jayaweera, M.D. (Dr. Jay)
Associate Vice Provost for Human Subject Research

Barbara Cole
Associate Vice President for Research Administration
Office of Research Administration (ORA)

- **Leadership:** Barbara Cole, *Associate Vice President, Research Administration*
  - **Pre-Award**
    - Jill Tincher, *Executive Director* **Phone:** 305-284-3952  **Email:** jtincher@med.miami.edu
  - **Post-Award**
    - Maria Amelia Garcia, *Director* **Phone:** 305-284-4022  **Email:** Garcia4@med.miami.edu
    - Maria Penton, *Director* **Phone:** 305-284-2375  **Email:** mpenton@miami.edu
  - **Strategic Initiatives**
    - *Allen Mora, Director*  **Phone:** 305-284-3906  **Email:** allen.mora@med.miami.edu
  - **Export Control & Technology Management**
    - TBA, *Export Compliance Officer*  **website:** www.miami.edu/exportcompliance
    - *Doug Horr (interim)*  **Email:** d.horr@miami.edu
    **Phone:** 305-284-3965
    **Email:** bacole@med.miami.edu
    **website:** www.miami.edu/ora
Office of Research Administration (ORA) Services

- **Pre-Award**: provides support for the identification of funding opportunities, proposal processing, and award negotiation.

- **Post-Award**: after the award is made and the grant proposal is funded, post-award is responsible for opening accounts, invoicing, expenditure compliance, subject tracking, and reporting, as well as closeout.

- **Strategic Initiatives**: assist the University research community with Systems, Reporting, Education and Training.

- **Export Control & Technology Management**: assists faculty and staff in the appropriate transfer of items, information, and equipment out of the U.S., or to a foreign national within U.S. territory.
Research Administration Evolution Underway

**PLANS**

- Create a “Big Science” unit
- Centralized oversight of proposals from smaller departments
- Unit-based oversight for larger departments/centers
- Provide training/networking opportunities for research administrators

**RESEARCH GOALS**

- Increase MSOM competitive advantage for Big Science funding
- Re-energize the grant portfolio
- Meet aggressive sponsored expenditure growth goals
- Increase our rankings

Phone: (305)243-6984  
Email: RBlunden@med.miami.edu  
Website: [http://research.med.miami.edu/](http://research.med.miami.edu/)  
Pre & Post Award
Regulatory and Compliance Services

Ensures that researchers comply with federal, state, and local regulations. Offices include:

- Research Compliance & Quality Assurance (RCQA)
- Disclosures & COI Management (DCM)
- Human Subject Research Office (HSRO)
- Institutional Animal Care and Use Committee (IACUC)
- Institutional Biosafety Committee (IBC)
- Embryonic Stem Cell Research Oversight Committee (ESCRO)
- Office of Environmental Health & Safety (EHS)
- Radiation Control
Office of the Vice Provost for Research

• **Leadership:**  John L. Bixby, Ph.D., *Vice Provost for Research*

• **Service:** implementation, maintenance and assessment of all research compliance activities; research support, including:
  
  – **conflict of interest:** financial disclosure and conflict of interest management;
  
  – **research integrity:** Investigates and resolves allegations of misconduct (*Cane Watch-Ethics Point*)
  
  – **research committee support:** IRB, IACUC, IBC & ESCRO
  
  – **research development:** support for centers, university-wide collaborative projects

Phone: 305-243-9635  
Email: JBixby@med.miami.edu  
Website: uresearch.miami.edu
Office of Research Compliance & Quality Assurance

- **Leadership:** Johanna Stamates, *R.N., MA, CCRC, CHRC, Executive Director*

- **Functions:** ensures compliance with research related processes and studies in human subject research by identifying compliance risks, preventing non-compliance and providing research compliance support
  - **Education & Training:** in a variety of Research Compliance-related areas including FDA Audit preparation, Clinical Trial Disclosure, Corrective Action Preventive Action (CAPA) plans, etc. Registration via [ULEARN](http://ulearn)
  - **Audits:** routine, directed, focused and follow-up GCP audits
  - **Federal Audit Support:** preparation of Principal Investigators and study teams for FDA, EMA, NIH audits. Assistance with responses to Form FDA 483 and FDA Warning Letters.
  - **Clinical Trial Disclosure:** development and implementation of university-wide structures to ensure compliance with Clinical Trial Disclosure requirements
  - **Corrective and Preventive Action System:** Creation and implementation of a University-wide CAPA system to ensure compliance with institutional and federal required CAPA plans.

  **Phone:** 305-243-4215
  **Email:** jstamates@med.miami.edu
  **Website:** [http://uresearch.miami.edu](http://uresearch.miami.edu)
Clinical Research Operations & Regulatory Support

- **Leadership:** Ann Glasse, RN, BSN, MBA- *Director*

- **Service:** supports clinical and translational investigators with PI-initiated IND/IDE studies and specific FDA-regulated processes:
  
  - **education & training:** provides a variety of research related training in areas such as Good Clinical Practice, informed consent process, etc. Registration via [ULEARN](#)
  
  - **monitoring:** conducts risk-based monitoring for PI initiated IND/IDE and federally funded studies
  
  - **regulatory support:** supports development and ongoing guidance of PI initiated Investigational New Drug (IND) & Investigational Device Exemption (IDE) submissions as well as project management support

  **Phone:** 305-243-6381
  **Email:** [CRORS@med.miami.edu](mailto:CRORS@med.miami.edu), [aglasse@med.miami.edu](mailto:aglasse@med.miami.edu)
Disclosures & COI Management, and Research Integrity

• **Leadership:** Lory Hayes, Ph.D., *Associate Director*

  • **conflict of interest**
    —education and training
    —review of relationships that pose potential COI
    —management of confirmed COIs
    —monitoring of compliance with executed management plans

• **research integrity** (Jerry Engel, J.D.)
  —education and training
  —investigates and resolves allegations of misconduct

  **Phone:** (305) 243-5036  
  **Email:** l.hayes@miami.edu  
  **Website:** uresearch.miami.edu
Institutional Animal Care & Use Committee – IACUC

- **Leadership:**  Sari Izenwasser, *Ph.D. Chair, IACUC*
  — Ellen Kapsalis, Ph.D., *Director, IACUC/IBC/ESCRO Office*

- **Service:** Provides oversight to ensure that faculty and staff comply with guidelines concerning the use of animals in research and teaching
  — reviewing and approving animal use protocols
  — training investigators and staff
  — inspecting animal facilities
  — monitoring animal research projects to ensure compliance
  — investigating concerns raised regarding care/use of laboratory animals

**Phone:** 305-243-2311  
**E-mail:** iacucsupport@med.miami.edu  
**Website:** uresearch.miami.edu
Human Subject Research Office (HSRO) – IRB

- **Leadership:** Dushyantha Jayaweera, Ph.D., *Associate Vice Provost for Human Subject Research*
  - Amanda Coltes-Rojas, M.P.H., C.I.P, *Director*

- **Service:** support for the UM institutional review boards (IRBs). IRB is a committee of faculty, staff and community members that reviews proposed human subject research to ensure the protection of those subjects and compliance with applicable federal regulations, state law and institutional policy.

HSRO facilitates human subject research at UM and supports the IRB.

**Phone:** 305-243-3195  
**Email:** DJayawee@med.miami.edu  
**Website:** [https://eprost.med.miami.edu/](https://eprost.med.miami.edu/)
Research Development

• **Leadership:** Karin Scarpinato, Ph.D., Assistant Provost, Research

• **Service:** Provide research support to faculty

  — Facilitate partnerships and collaborations: internally, nationally and globally
  — Support multi-investigator program projects and grants
  — Identify and evaluate funding opportunities
  — Center/Institute support
  — Research Support: Cores & Shared Resources
  — Limited Submissions
  — Research Communication

  **Phone:** 305-243-1660  
  **E-mail:** kds44@miami.edu  
  **Website:** uresearch.miami.edu
Collaborative Institutional Training Initiative (CITI)

- **Leadership:** Paul G. Braunschweiger, Ph.D., Director and Co-Founder

- **Service:** The CITI Program at the University of Miami offers web-based training and education in multiple areas of research ethics and compliance. Online course offerings include:
  
  — animal care and use
  — biosafety and biosecurity
  — clinical research coordinator
  — export compliance
  — disaster planning for the research enterprise
  — good clinical practice (GCP)
  — good laboratory practice (GLP)
  — human subjects protection
  — information privacy & security
  — responsible conduct of research (Biomedical, Engineering, Humanities, Social and Behavioral, Physical Sciences, Research Administration)
  — conflict of interest (COI)

Phone: 305-243-3922  
E-mail: citisupport@med.miami.edu  
Website: [http://www.citiprogram.org/](http://www.citiprogram.org/) (password required)
Office of Research IT

- **Leadership:** David Seo, M.D., *Chief Research Information Officer*
  - Stephen DeGennaro, *Director*

- **Service:** provides support, configuration, and training on institutional enterprise systems that enable research administrative and training processes; activities include:
  - process/systems analysis, requirements gathering, technology evaluation
  - IT project management
  - information system custodians
  - end-user support & training
  - software maintenance, configuration, documentation, QA, testing
  - system interfacing & integration
  - strategic planning involving technology to achieve enterprise goals

**Help Desk:** 305-243-2314  
**Email:** resinfo@med.miami.edu  
**Website:** http://uresearch.miami.edu/research-resources/research-information-technology
What systems does Research IT support?

<table>
<thead>
<tr>
<th>Software</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Velos eResearch</strong></td>
<td>Enterprise clinical trial management system used for tracking study participants, related data collection, and sponsor invoicing for IRB approved protocols.</td>
</tr>
<tr>
<td><a href="https://velos.med.miami.edu">https://velos.med.miami.edu</a></td>
<td>• Helps facilitate key study team activities, support industry trends and comply with UM policy.</td>
</tr>
<tr>
<td></td>
<td>• Track roster of study subjects, associated statuses, visit schedule, procedures completed, adverse events, data collection via electronic data capture forms.</td>
</tr>
<tr>
<td></td>
<td>• Prepare invoices for sponsors and reconcile payments received.</td>
</tr>
<tr>
<td></td>
<td>• Report on protocol compliance, data quality assurance, prepare summaries for regulatory submissions.</td>
</tr>
<tr>
<td></td>
<td>• Comply easily with University policy for subject tracking notifications</td>
</tr>
<tr>
<td><strong>Key Stakeholders:</strong> Researchers/PI’s/Study Teams</td>
<td></td>
</tr>
</tbody>
</table>

| **Electronic Protocol Submission & Tracking** | The eProst (Electronic Protocol Submission and Tracking) system is the Human Subject Research Office's (HSRO) web-based, computer system that automates the entire lifecycle of human subject research activity. |
|  https://eprost.med.miami.edu | • Designed to support both behavioral and biomedical research studies, including studies requiring IRB approval by the full panel.                      |
| **Key Stakeholder:** HSRO/IRB - Dr. Jayaweera |                                                                                                                                                                                                             |
What systems does Research IT support?

<table>
<thead>
<tr>
<th>Software</th>
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<th>Key Stakeholder: <strong>Office of Research Administration (ORA) - Barbara Cole</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>InfoEd eRA Portal</strong></td>
<td>Suite of research administrative tools that support electronic proposal development, proposal tracking, and IACUC protocol tracking. Used by the University of Miami for finding funding; preparing, submitting, tracking, and managing proposals; and for managing lab animal protocols. Includes tools to search for funding opportunities as well as tools to match available funding opportunities to Principal investigators.</td>
<td></td>
</tr>
<tr>
<td><a href="https://infoed.med.miami.edu">https://infoed.med.miami.edu</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Disclosure Profile System</strong></td>
<td>The DPS streamlines into one simple process several of the current UM disclosure processes, combining the Faculty Disclosure Form (FDF), the Financial Interest Declaration (FID) form and the Individual Interest Disclosure (IID) form in order to support UM compliance policies and comply with federal regulations.</td>
<td><strong>Key Stakeholder: Office of Disclosures and COI Management (DCM) - Lory Hayes</strong></td>
</tr>
</tbody>
</table>
What systems does Research IT support?

<table>
<thead>
<tr>
<th>Software</th>
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</thead>
</table>
| Topaz Granite, Web Animal Orders, Mobile Census  
https://wao.med.miami.edu | System used for tracking lab animal orders, current animal inventory (census), and DVR invoicing.  
*Key Stakeholder:* IACUC/DVR – Dr. Ellen Kapsalis |
| Clinical Trial Search  
http://Uhealthclinicaltrials.com | Homegrown, web-based tool provided to care providers, potential subjects, or family members for finding actively recruiting therapeutic studies at UHealth.  
*Key Stakeholder:* Public |
| Graduate Studies System  
https://gradstudies.med.miami.edu | Homegrown, web-based system for tracking biomedical research trainee progress toward their degree, related graduate faculty participation, and program admissions as well as T32 data table creation.  
*Key Stakeholder:* OGS – Dr. Nawaz |
| Research Reporting System  
http://research.miami.edu  
http://experts.scival.com/miami | Institutional reporting dashboard for extramurally funded scholarly activity and lab animal usage. Includes sponsored programs financial information and compliance reporting (managed by ORA)  
*Key Stakeholder:* ORA - Barbara Cole |
| UM RedCap  
https://Redcap.med.miami.edu | REDCap is a secure, web-based application for building and managing online surveys and databases. Recently implemented, RedCap offers a convenient alternative to rapid eCRF development for study teams and researchers across the University.  
*Key Stakeholders:* Researchers/PI’s/Study Teams |
Research Resources

The University of Miami maintains a variety of specialized facilities, services, and instrumentation to support the research and education enterprise. These services include:

- Division of Veterinary Resources
- core facilities & shared resources
- Clinical Translational Research Site
- ethics programs
- Office of Technology Transfer
- Clinical Research Operations & Regulatory Support
- internal funding opportunities
- internal pre-review grants and specific aims
- research listservs
Office of Core and Shared Resources (OCSR)

- **Manager:** Monica Flores

- **Service:** The OCSR, located in the UMMSM Office of Research, Research Education, and Innovative Medicine, promotes efficient use of technologies by facilitating access to laboratory, translational, and clinical core facilities and shared resources. Most of these resources operate as recharge centers and are accessible on a fee-for-service basis.

  **Phone:** 305-243-2836  
  **Email:** OCSR@med.miami.edu or  
  **Website:** http://uresearch.miami.edu/cores/ (includes a listing of UM Core Facilities and Shared Resources):
Clinical Translational Research Site

- **Leadership:** Matthias Salathe, M.D., Director
  - JoNell Potter, Ph.D., RN/ARNP, Associate Director
  - Halina Kusack, R.N., Nurse Manager
- **Service:** provides clinical research infrastructure to investigators, including services, instruments, and facilities. Areas of service include:
  - Nursing
    - vital signs
    - phlebotomy
    - medication administration (IV, oral, etc.)
    - Pharmacokinetic studies
    - glucose tolerance test (oral or IV)
    - study specific assessments
  - Laboratory
    - specimen collection & processing
    - specimen storage and shipping
  - Body Composition
    - anthropometry (circumference, skinfold)
    - impedance analysis
    - bone density
  - Other (pulmonary function testing)

**New location in UMH (7 South)**

- new research infrastructure
- integrated inpatient/outpatient unit
- overnight stays

**Phone:** 305-243-5012
**Website:** [http://research.med.miami.edu/clinical-research/ctrs](http://research.med.miami.edu/clinical-research/ctrs)
Institute for Bioethics and Health Policy

- **Leadership:** Kenneth W. Goodman, Ph.D., *Director*
- **Service:** education, research and community service in ethics and the professions. Programs include courses, conferences, research projects, seminars and other activities around UM and with partners throughout Florida, the United States and around the world.
- **Emphases:** Bioethics and research ethics, including social responsibility, and with foci on information technology and international issues.

**Phone:** 305-243-5723  
**Email:** ethics@miami.edu  
**Website:** [http://www6.miami.edu/ethics/](http://www6.miami.edu/ethics/)
Office of Technology Transfer (OTT)

- **Leadership:** Norma Kenyon, Ph.D., Vice Provost for Innovation
- **Service:** The OTT’s mission is to:
  - maximize the value of intellectual property developed at UM by identifying, protecting and commercializing discoveries and inventions to save lives, improve the quality of life and benefit the public in compliance with the Bayh Dole Act.
  - generate revenue for UM to support education, research, and the charitable mission of the University.
  - foster the economic development of the local community.

  **Phone:** 305-243-5689  
  **Email:** NKenyon@med.miami.edu  
  **Website:** [http://www.med.miami.edu/uminovation/](http://www.med.miami.edu/uminovation/)
Clinical and Translational Science Institute (CTSI)

**Goal**: speed translation of research into practices that improve health
- training, education, & career development for researchers, staff
- provide individualized research services, consultation, and funding
- strengthen team science, research collaboration, and community-research partnerships
- identify institutional barriers to research and help develop new methods to overcome them

Promotes “Culturalized Health Sciences”, culturally-competent research to reduce health disparities disproportionately affecting South Florida’s diverse population.

**For further information:**  [www.miamictsi.org](http://www.miamictsi.org)
School of Medicine Internal Awards Programs

• **Leadership:** Dalton Dietrich, Ph.D., *Senior Associate Dean for Translational & Discovery Science*

• **Service:** designed to foster excellence in research and creative scholarship at the University of Miami Miller School of Medicine (UMMSM).

*Scientific Awards Committee (SAC) programs include:*

– **Interdisciplinary Team Science (ITS) Pilot Program Awards:** $50,000 up to a maximum of $75,000 in direct research to assist faculty members in developing new research projects with an emphasis on interdisciplinary science. A letter of intent (LOI) is required before submission of a full proposal.
  - should involve the synergistic collaboration of two (2) or more investigators
  - should represent new areas where the applicant team has no current funding/publications, or
  - new and/or expanded direction(s) for existing programs, where made possible by collaboration.

– **pilot awards:** $25,000 to jumpstart new research areas

– **bridge awards:** $30,000 to assist faculty in maintaining their current research program in the event of a funding lapse during the process of applying for extramural funding
School of Medicine Internal Awards Program

**Administrative Committee (AC) programs include:**

- **emergency equipment awards**: $20,000 to replace or repair intensively used equipment that unexpectedly breaks down or to upgrade existing equipment

- **research support award grants**: $25,000 in direct research costs per year for a 12-month period (may be extended to a maximum 24 month period if fully justified) and cover unanticipated shortfalls in research funding that impede the progress of a proposal submission or funded research. This award should be applied for only when no other internal award mechanism is appropriate.

- **grant editing support grants**: $1,500 for external consulting when an investigator is in the final stages of proposal submission and in rare cases for the early development stage of a proposal. The expectation is that a proposal will be submitted to an external sponsor following the expenditure of the award.

**Dean’s NIH Bridge Program**

- applicant must hold a primary appointment at the UMMSM and have been the PI on an NIH R or P-type “funded” grant application. P-type grants will be considered, but only the research related sub-projects are eligible for consideration
School of Medicine Internal Awards Program

— applicant’s most recently submitted NIH R or P-type grant application must have been unfunded
— applicant’s most recently submitted NIH R or P-type grant application must have scored within 15% of the pay line
— any PI incentive program dollars and/or no-cost extension funds must be exhausted

Stanley J. Glaser Research Foundation Awards

— seed funding for young investigators to enable them to compete successfully for major federal grants – by invitation only
— UMMSM assistant professors below the age of 45

Phone: 305-243-5370
E-mail: Klamper@med.miami.edu
Website: http://uresearch.miami.edu/funding-opportunities/internal-awards/miller-school
CTSI Funding Opportunity: Grant Resubmission Awards Program

Designed to support scored grant applications submitted to national level agencies. Goal is to strengthen innovative, translational, interdisciplinary, and health disparities-oriented proposals for resubmission (as an A1 or new grant).

Criteria:

- R21 and R01 scored applications in prior 2 years
- award amount: $25,000 per year
- award period: June 1, 2015 – May 31, 2016
- number of awards: 3 awards were given in April 2015

Next cycle to be announced in Fall 2015
CTSI Funding Opportunity: K12

Mentored Translational Research Scholars (K12)

- supports promising early-career investigators
- focus on research programs examining disease processes or outcomes related to health disparities that disproportionately affect South Florida’s highly diverse racial/ethnic population.
- provides “protected time” and a structured research training program under the guidance of a mentor.

Two KL2 (K12) awards were given in April 2015
The next KL2 RFA will be announced in Fall 2015
Research Listservs

Research listservs are the primary communication tool for the research community. The listservs are resources you can use to leverage the collective knowledge of the University to help you solve problems and improve the effectiveness of your research operations:

– **research listserv**: Read about new funding opportunities and updates to policies and procedures from external funding agencies and the University. You may also post questions, and find collaborators and specialized resources.

– **research administrators listserv**: Read about new funding opportunities and updates to policies and procedures from external funding agencies and the University. You may also post questions and connect with other research administrators.

– **clinical research listserv**: Join this listserv for human subjects’ researchers to learn about new policies, training and education opportunities, and process changes from the University. Share information on clinical research, and find collaborators and specialized resources.

– **international research listserv**: This listserv targets University faculty, staff, and students engaged in international research and permits subscribers to post questions and share information on topics of interest related to international research.

**Website:** uresearch.miami.edu
Summary

- doing research is complicated well beyond the science
- infrastructure helps researchers navigate AND ensures protection of subjects/regulatory compliance
- all researchers, not just PIs, have multiple responsibilities
- if you have questions, ask
  - Miller Office of Research, Research Education and Innovative Medicine
  - Office of Research Administration
  - Human Subject Research Office
  - Office of Research Compliance and Quality Assurance
  - Clinical Research Operations and Regulatory Support
  - Office of the Vice Provost for Research

UNIVERSITY
OF MIAMI