Clinical Research Office (CRO)

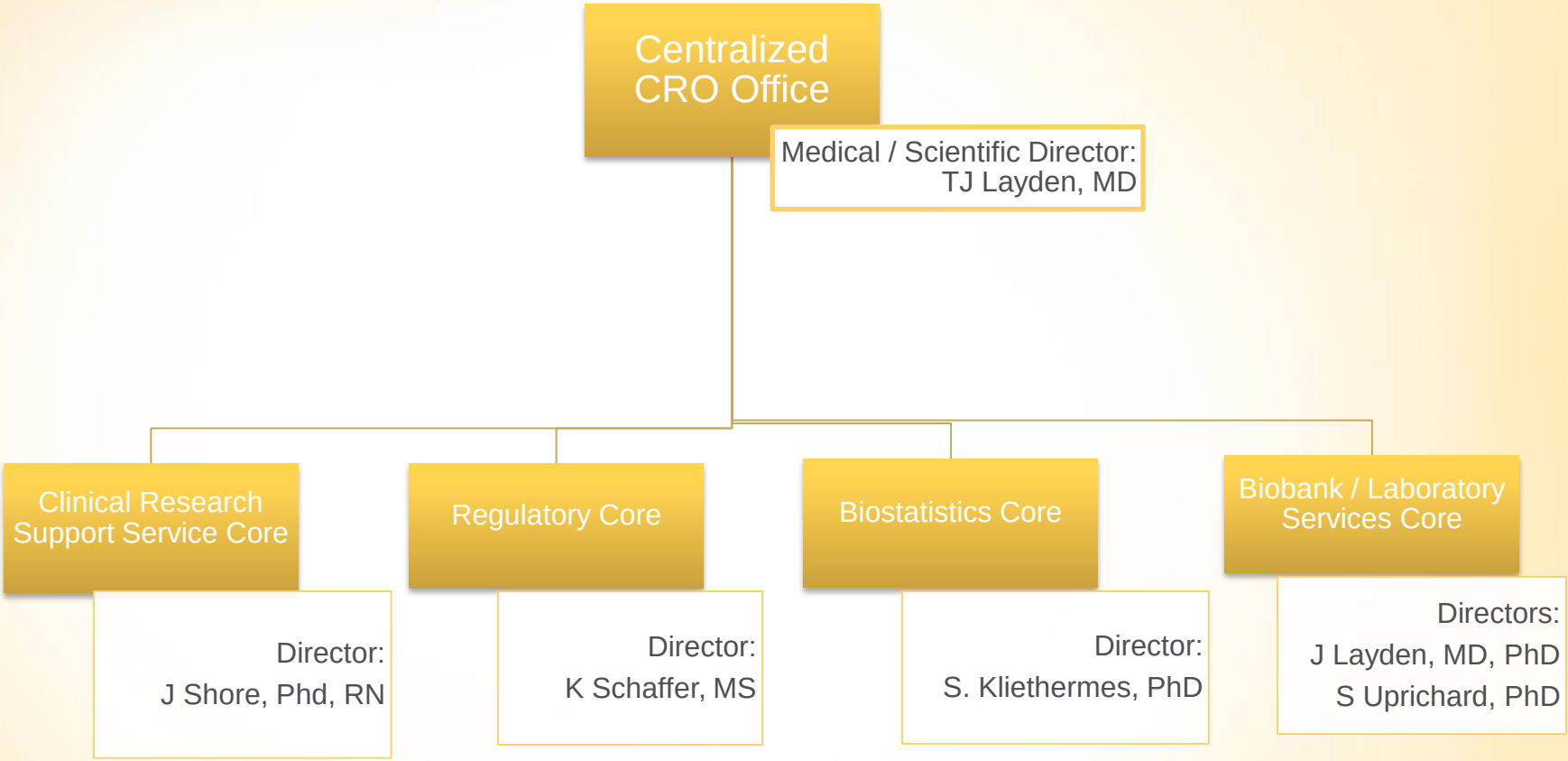
Established: 10/2012

Director: Tom Layden, MD

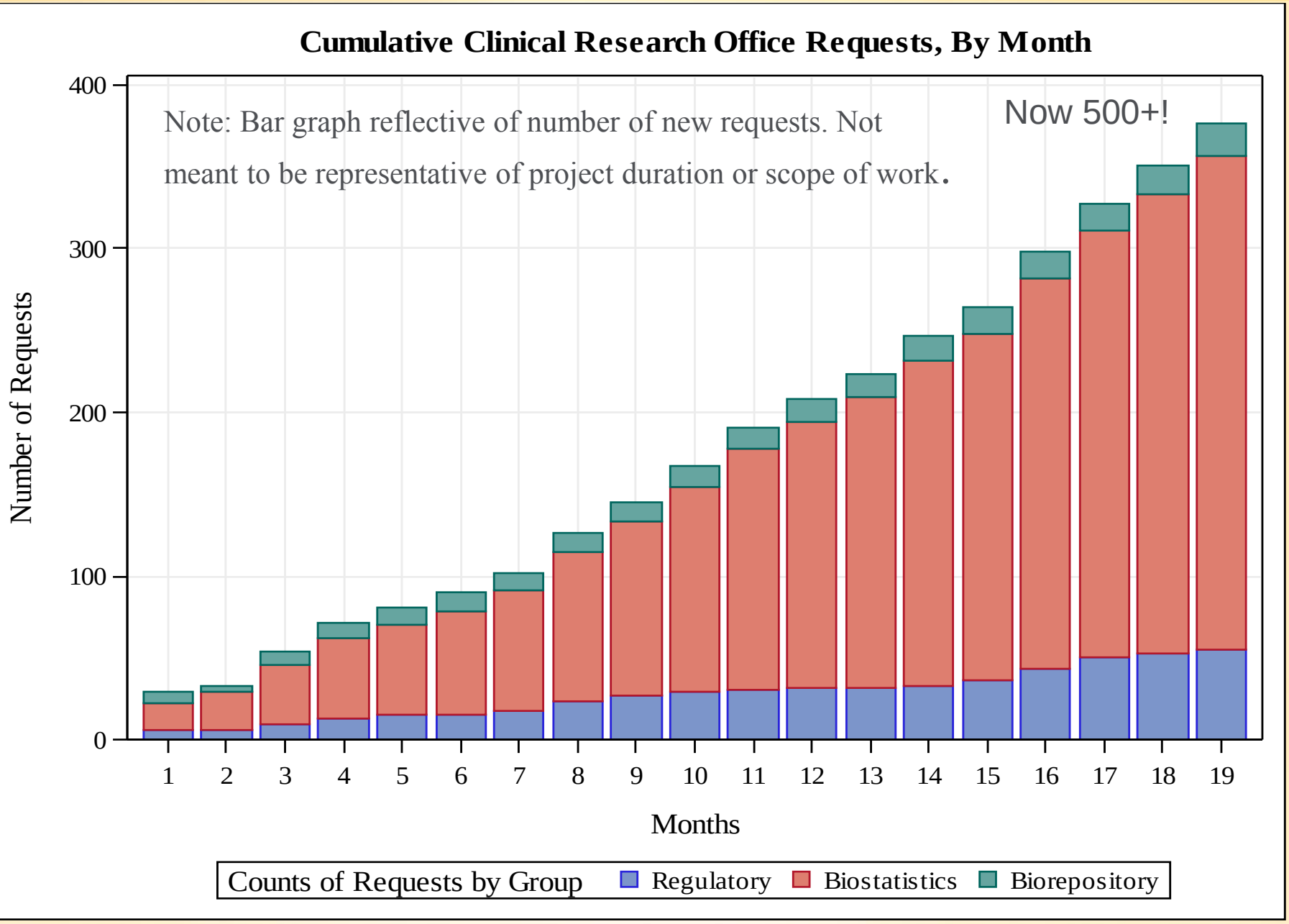
Mission: Our mission is to strengthen Loyola clinical research by providing infrastructure, services, and mentorship that can assist new and established investigators through every stage of the research process, from grant submission and protocol development through data collection, analysis, and publication.

Current Organizational Chart for Clinical Research Office (CRO):

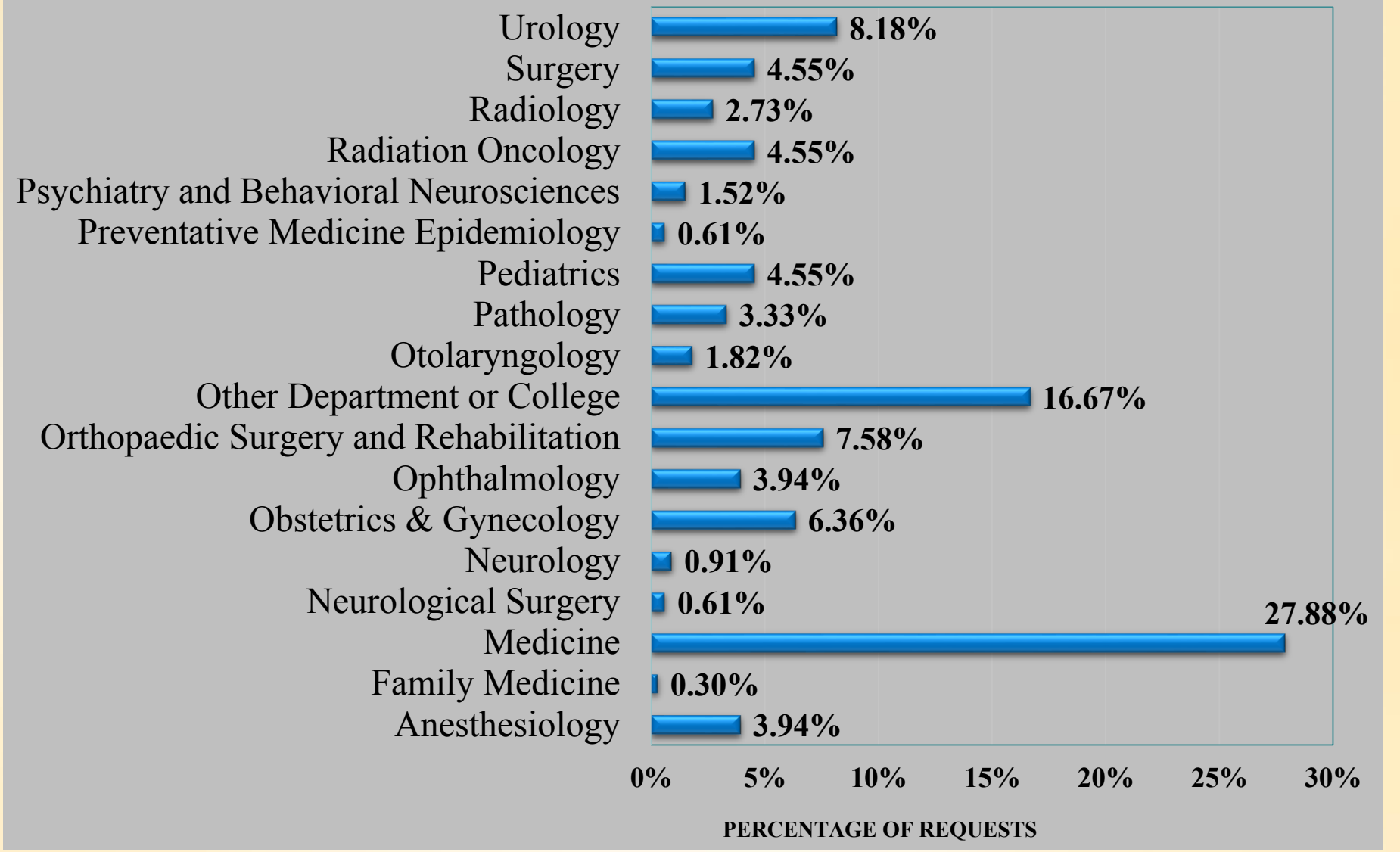
LOYOLA MEDICINE



Initial Funding from LUMC


Cumulative Clinical Research Office Requests, By Month
Note: Bar graph reflective of number of new requests. Not meant to be representative of project duration or scope of work.
Now 500+!
Number of Requests
400
300
200
100
0
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
Months
Counts of Requests by Group
Regulatory
Biostatistics
Biorepository

Clinical Research Office Requests by Department



Biostatistics Core

LOYOLA MEDICINE

- **Purpose:** provides biostatistical consultative and collaborative support to faculty, staff and students pursuing clinical research across the Loyola University health sciences campus.
- **Members:**
  - Director: S Kliethermes, PHD
  - Team: 2 MS biostatisticians, 2 junior level statisticians, rotating practicums/volunteers
  - Evolving……
- Services:
  - collaboration and consultation
  - study design, sample size / power calculations, statistical analyses, database development and management via REDCap, grant proposals, manuscript preparation, and teaching
- Utilization: 5 / week; Since 1/2015: over 500 requests
- Grant / Financial support: RFC, NIH, AHA, VA Merit, PCOR, Leischner Institute, STAR program

Biostatistics Core (cont)

LOYOLA MEDICINE

- Biostatistical Requirements / Involvement for studies has increased in complexity
  - eg: PCOR grants
- Ideal to be involved from study development stage

Clinical Research Support Services Core

LOYOLA MEDICINE

- **Purpose:** provides assistance with the contracting and budgeting phases of clinical trials, study start-up, completing the IRB submission process, sponsor regulatory approval processes, and providing study coordinator services
- **Members:**
  - Director: J Shore, RN, PhD
  - Team: Clinical Research Nurses, Clinical Protocol Coordinators and Financial Coordinator
- Services:
  - Attending pre-site and investigator meetings, Start up activities, Developing and obtaining informed consent, Conducting study visits ,Collecting and recording data, Completing case report forms, Obtaining biological specimens, Coordinating processing, storing, and shipping of samples via the CRO Biobank, Maintaining regulatory documents, Participating in study monitor visits , Close out activities
  - Works closely with investigators, sponsors, contracting, and IRB
- Utilization:
  - Currently >40 clinical research protocols
  - Numerous HSD Departments

Regulatory Core

LOYOLA MEDICINE

- Purpose: Offers regulatory services for both industry-initiated and investigator-initiated research projects. The Regulatory Core works with investigators on IRB submissions, IND and IDE documentation to the FDA, and also conducts quality assurance activities for the studies supported by the CRO. We serve as a resource to investigators and study teams on regulatory issues and research conduct.

- Team: Regulatory Manager: K Shaffer, MS
  - works with other CRO cores
- Services:
  - IRB submission of new protocols, annual continuing reviews, amendments, adverse events, protocol deviations, and other mandatory reporting (e.g. noncompliance).
  - Preparation and negotiation of informed consent documents.
  - Completion and maintenance of ancillary requirements including study sponsor and FDA regulatory documents
  - Assist in protocol development and design in collaboration with other CRO cores
  - Investigational New Drug (IND)/ Investigational Device Exemption (IDE) applications, FDA reports
  - Maintain clinicaltrials.gov data
  - Serve as resource to investigators and study teams on regulatory research conduct
  - Act as liaison between affiliate institutions, study sponsors, contract research organizations, study coordinators, study monitors, and investigators regarding study progress and procedures
  - quality assurance activities to ensure protocol compliance for the studies supported by the Clinical Research Office
  - Work in close collaboration with Biorepository Core and Sponsored Clinical Research Core

Biobank Core

LOYOLA MEDICINE

- Purpose: centralize tissue acquisition, storage, and facilitate distribution of samples for future research purposes with proper authorization. The initial objective was to create a meaningful and lasting repository of carefully collected and controlled bio-specimens with relevant accompanying clinical data.

- Team: Directors: J Layden, MD, PhD; S Uprichard, PhD
  - Team: Biobank Manager (in transition); Technician: K Carey
- Services:
  - Assist in protocol development and consent language
  - Work with the Regulatory Core to ensure proper consent and regulatory compliance is maintained
  - Determine logistics for sample procurement
  - Collaborates with Pathology Dept. to collect fresh and FFPE tissue per protocols
  - Serve as resource to investigators and study teams on sample handling and processing procedures
  - Process clinical research samples per protocol (basic centrifuging and aliqouting, serum/plasma separation, DNA / RNA extraction from fresh or frozen blood or tissue)
  - Catalog and store clinical research samples under secure conditions
  - Maintain sample management database (Freezerworks)
  - Prepare and ship research samples
  - Sponsored Clinical Trials Lab Processing/Storage: Process central lab kits per protocol specific lab manual, including: Spin down tubes and aliquot samples, Prepare slides for hematology central lab analyses; Prepare ambient and frozen samples for shipment per IATA requirements; Coordinate shipping with study team

Biobank Core (cont)

LOYOLA MEDICINE

- Essential Components:
- CRO-Biorep follows federal guidelines (http://www.hhs.gov/ohrp/policy/reposit.html)
  - *Confidentiality / HIPPA compliance*
  - *Sample Integrity / Security*
  - *Sample distribution*
- 2nd standard Biobank consent for long term storage
- Unique identifier: SMART-ID
- NIH Certificate of Confidentiality
- Data usage agreements
- Security / Monitoring: Alarm System (email, phone), Back up freezers, C02 tanks
- CAP accreditation

Biobank Core

LOYOLA MEDICINE

- Utilization:
  - CRO-Biorep: LU#204853
  - CRO-Blood Draw Protocol LU#204976: Purely for future use
  - Numerous investigator initiated studies
    - Some have additional consent for future use
  - Departments: Medicine, Surgery, Urology, Nursing, Pediatrics, Ophthalmology

Junior Investigator Support

LOYOLA MEDICINE

NAME	DEPT	BIOSTATS	BIOBANK	COORD.	REGULATORY	RFC	NIH/VA/Other	NIH-LR
M Afshar MD, MS	MED/PH	Y-$	Yes--$	Yes-$	YES	YES 1-15	K-23 subitted 10/15	Yes
J Layden MD/PhD	PH/Med/ID	Yes--$	Yes-$	No	YES	Yes-2015	Gilead/PCOR and NIH pending	Yes
M Fitzpatrick, MD	MED/ID	Yes-$	Yes--$	Yes-$	YES	Yes-2015	VA Fellowship/ K 6/16	Yes-app
C Brincat MD	OB/GYN	Yes-$	N	No	No	Yes-2015	RO-3—Submitted	no
A Goldberg MD/PhD	Radiology	Yes-$	N	Yes--$	Yes	No	Industry/NIH pending	no
C Fitzgerald, MD, MS	OB/RehAB	Yes-$	No	Yes-$	No	No	K23; NIH pending	yes
E Kallwitz MD	Med	Yes-$	Yes--$	Yes--$	Yes	Yes-2014	AASLD	yes
M Ma MD	Pediatrics	Yes-$	Yes--$	Yes-$	Yes	Yes-2014		yes
G Gupta MD	URO	Yes	Yes	No	YES	No	NIH pending	yes
K Hutchins MD	Pathology	No	No	No	No	Yes-1/15	No	yes
S Byram MD/Phd	Anaest.	Yes	No	No	No	No	VA resub 2/16	yes

Junior Investigator Support

LOYOLA MEDICINE

NAME	DEPT	BIOSTATS	BIOBANK	COORD.	REGULATORY	RFC	NIH/VA/Other	NIH-LR
Erin Lowery MD	Med/Pulm	Yes-$	Yes--$	Yes	Yes	Yes-2013	NIH K23	yes
Talar Markosian PhD	PH	No	No	Y-$	No	No	R21 and PCOR pending	no
Ahmer Farooq	Uro	No	No	Y-$	Yes	Yes-10/15	Potential VA Merit	no
Lara Dugas PhD	PH	Yes $	Yes-$	No	No	No	RO-1 2/16	no
Dana Hayden MD	Surgery	No	No	No	No	RFC--3/16		no
Erin Coglianese MD	Med	Yes	Yes	Yes	Yes	Sub-16		no
Stephanie Kliethermes	PH					No	NIH, RFC	no
A. Dadarajan MD	Med/Onc	No	Yes	Yes	Yes	No	ND/LU	no
S. Borowitz MD	Med/Onc	No	No	No	No	No	VA Career	no
S. Scaglione	Med/Liver	Yes-$	Yes	Yes	Yes	RFC/NF		no
S. Akina MD	Med/Neph	Yes-$	Yes $	Yes $	Yes $	Yes-9-16	NIH k23 completed	no

Junior Inv Support

LOYOLA MEDICINE

-Mentoring

- VA / LUC Mentoring program
- NIH Loan Repayment Program (7)
- RFC Grants (8)
- Grant writing seminars
- Grant external review
- RedCap training

Senior Investigators

LOYOLA MEDICINE

SENIOR INVESTIGATORS AT HSD INVOLVED WITH CLINICAL RESEARCH AND USE OF CRO

NAME	DEPT	BIOSTATS	BIOBANK	COOD	REG	GRANT(s)
Amy Luke PhD	Public H.	Yes-5% SK	No	No	No	NIH-RO-1 sub Oct 2015
P. Camacho	Med/Endo	Yes	No	Yes	No	Sponsored clinical research
H. Kramer MD	Med/PH	No	Yes	No	No	NIH pending
A Wolfe/L.Brubaker	Micro/Ob	Yes-SK 10%	Yes	No	Yes	NIH-P20 and RO-1
Susan Uprichard PhD	Med/Liver	Yes-SK 5%	Yes	No	No	VA Sub. 10/15
S. Penkhofer PhD	Nursing	Yes-WA 10%	No	No	Yes	RO-1 Funded
Sadayappan	Physiology	Yes 3%	No	No	Yes	RFC
P Stiff MD	Med/Onc	Yes	No	No	no	Cancer Protocols
E. Wojik MD	Path	Yes	Yes	No	No	Urinary Cytology
A. Bidani MD	Med/Neph	Yes-5%	No	No	No	VA Merit-sub. 2016
G. Hecht MD	Med/GI	No	No	Yes	Yes	Sponsored Clinical res
D. Dilling MD	Med/Pulm	No	Yes	No	Yes	Multiple Clinical Trials
J. Cook MD	Med/ID	No	No	No	Yes	
Gruener	Sch. Med.	Yes >50%	No	No	No	Leischner
D. Wilbur MD	Med/Cardio.	Yes	No	No	No	Cardiac Arrythmia
S Cotler	Med/Hep	Yes	Yes	Yes	Yes	

Funding

LOYOLA MEDICINE

- Initial Support from LUMC
- Grant Support
  - On NIH grants that total over $1.5 M direct dollars
    - ~150,000 salary support of CRO staff
  - $3 M direct dollars NIH grants pending
  - Industry trials/studies-full re-coup of CRO service
  - Additionally on VA, PCOR, and Foundation grants

Educational Support

LOYOLA MEDICINE

- STAR Program
- Resident / Fellow Programs
- Medical Student Programs

Future Growth

LOYOLA MEDICINE

- Moving to CTRE!
  - Biostats, Regulatory, Study Support Services: 2nd floor
  - Biobank: 1st floor
- Support
  - LUC and LUMC
- Growth

Acknowledgements

LOYOLA MEDICINE

- LUMC
  - D Hecht, MD and L Goldberg, MD
- Scott Cotler, MD
- SSOM/HSD
- CRO Director, Core Directors, and Staff

- http://ssom.luc.edu/cro/