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WELCOME TO THE MEMBER RETREAT
& ADVISORY BOARD MEETING
June 23, 2014

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Retreat Objectives

- Conduct an inclusive, strategic planning session that informs CFAR decision-making.
- Maintain open lines of communication between members, stakeholders, and leadership.
- To create opportunities for scientific networking and collaboration.
- Agenda includes:
 - ✓ A summary of current CFAR Cores & Services
 - ✓ Results of Faculty Survey
 - ✓ Advisory Board Feedback

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Overview and
Developmental Core

Michael Keefer, CFAR Co-Director,
Director of Developmental Core

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CFAR Mission

To provide leadership, services & infrastructure to:

- Establish multidisciplinary collaborations that achieve high-impact discoveries
- Support early career development of young HIV/AIDS investigators
- Establish a distinctive scientific identity, placing the UR at the forefront of HIV/AIDS research

Services organized within four cores: (1) Developmental, (2) Clinical and Translational Sciences, (3) Basic Sciences and (4) Biostatistics, Bioinformatics and Computational Biology Core

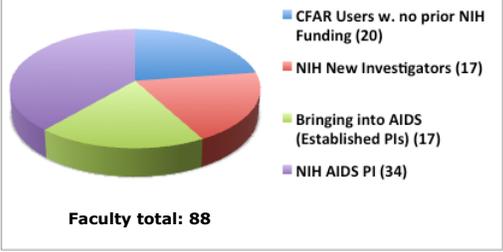
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CFAR Membership



■ CFAR Users w. no prior NIH Funding (20)

■ NIH New Investigators (17)

■ Bringing into AIDS (Established PIs) (17)

■ NIH AIDS PI (34)

Faculty total: 88

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Developmental Core
Stimulating New Research

Pilots Awards (\$20,000-40,000 DC)

- Young faculty members
- Innovative studies with potential for high impact
- Multidisciplinary collaborations

NIH Supplement Funding (\$100,000)

- Funding for a broad range of projects to address key gaps in understanding of HIV/AIDS
- Support early stage investigators or well established investigators in non-HIV fields

Microgrants (\$2,500)

- To advance research objectives on existing NIH-funded research activity, or generation of preliminary data for planned applications

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Developmental Core

Career Development of Young Faculty/Faculty New to HIV/AIDS

CFAR Pilot/Supplement Proposal Critical Review

- Internal application review
 - Opportunity to discuss with members of review committee, with goal of revising and improving proposal

Mentoring

- Multidisciplinary mentoring from a diverse mentorial team
- Cross-departmental: Scientific/Technical and/or Career development

Grant Review Service

- Increase competitiveness of extramural proposals (new investigators, established investigators new to HIV/AIDS)
 - Proposal Shaping Phase
 - Proposal Refinement Phase
 - Responding to Review Committee Critiques

Prospective Outreach to Investigators

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Developmental Core

Recent Grant Award Successes (Jr. Faculty)

Pilot Awards & Microgrants

- 2013 Pilots: Amina Alio, James Kobie, Dorota Piekna, Jharon Silva
- 2014 Pilots: Dorota Piekna, Jian Zhu, Sherry Spinelli
- 2014 Microgrants: Krupa Shah, Cindi Lewis

CFAR Supplements, Related Awards

- 2012: CNIHR award (\$450k) – Rusty Elliott
- 2013: Supplements (\$100k) – Theresa Senn (Brown U. w. UR); Tinashe Mudzviti (U-Zimbabwe, w UB/UR)
- 2014: Supplements (pending) – LaRon Nelson, Juilee Thakar, Hill Kutscher (UB), Izukanji Sikazwe (U. Zambia w. Gretchen Birbeck)

Other Extramural Awards

- 2013: K23 awards (~\$600k) – Diane Morse, Krupa Shah
- 2014: Clinical Trials Unit renewed w. help from CFAR

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Developmental Core

Enriching the Scientific Environment

HIV/AIDS Related Symposia

- World AIDS Day
 - Initiated in 2009
 - Keynote Addresses/Poster Sessions
 - Community Outreach Programs
- Other (i.e., 'Justice Involved Women', 'HIV for the Primary Care Provider')
 - Researchers, practitioners and policy
 - Disseminate evidence-based practices and intervention

Interdisciplinary Seminars (~30/year)

- Multidisciplinary, cross-campus series
- Integrated into existing departmental programs

Courses and Workshops

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Developmental Core

Future Plans (Selected)

Pilot Awards

- New RFA planned for fall 2014 (in collaboration with our SWGs)

Mentoring: Grant Preparation Support

- Continued expansion of this service, using scheduled steering committee meetings (and additional meetings)

Mentoring: Team Science/Collaboration

- Support CTSC & Development Networking Event in fall 2014
- Speed-dating event for RNA SWG (Ctr for RNA Biology & established HIV investigators)
- Engagement w. optics/imaging scientists

Other

- User satisfaction survey planned for fall 2014

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Developmental Core

Key Contacts:

Michael Keefer, Core Director
Steve Dewhurst, Associate Core Director
Benjamin Miller, Associate Core Director
Jennifer Lynch, Program Administrator

Website

<http://www.urmc.rochester.edu/cfar/services-cores/developmental.cfm>

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Clinical and Translational Sciences Core (CTSC)

James McMahon, PhD
Amneris Luque, MD
Co-Directors

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CTSC Core

Key Administration:

Amneris Luque, Co-Director
James McMahon, Co-Director
Mike Keefer, Oversight Committee Chair
LaRon Nelson, Assoc Dir International Research
Jennifer Lynch, Program Administrator
Catherine Bunce,
Emily Cosimano,

Website
<http://www.urmc.rochester.edu/center-for-aids-research/services-cores/clinical-sciences.aspx>

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CTSC Mission

To provide key services to UR investigators to promote collaborative clinical and translational research in areas that impact upon the spread, treatment and control of HIV/AIDS

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Clinical and Translational Research Model

T0	T1	T2	T3	T4
Basic and applied science research	Translation to humans	Translation to patients	Translation to practice	Translation to community
Preclinical and animal studies	Proof of concept Phase 1 clinical trials	Phase 2 clinical trials Phase 3 clinical trials	Phase 4 clinical trials and clinical outcomes research	Population level outcome research
Defining mechanisms, targets and lead molecules	New methods of diagnosis, treatment and prevention	Controlled studies leading to effective care	Delivery of recommended and timely care to the right patient	True benefit to society

Blumberg et al. Nature Medicine 18:35-41; 2012

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CTSC Model

Clinical and Translational Sciences Core

- Bench to Bedside Unit**
 - A. Luque (Chair)
 - Regulatory Support
 - Study Coordination
 - Recruitment & Outreach
 - Custom Cohort Services
 - HIV Patient Registry
 - HIV Patient Bio-specimen Services
 - Mentoring/Education
- Community Outreach Unit**
 - A. Luque (Chair)
 - CBPR/Disparities Research
 - Medical Provider Education in "Research Literacy"
 - Impacted Communities
- Population Sciences Unit**
 - J. McMahon (Chair)
 - Community-Based Public Health Research
 - Outcomes Research
 - Social Network Analysis
 - Mentoring/Education
 - Collaboration

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CTSC Core Services

Regulatory Support

- Preparation of clinical protocols, consent forms, procedures, data safety and monitoring plans
- Guidance and support available for protocol planning and implementation:
 - Reporting of adverse events
 - Preparation of annual IRB reports
 - Study close-out procedures

Study Coordination and Operational Services

- Hands-on assistance in setting up and maintaining best practices
 - Preparation of manuals and training procedures
 - Tailored to needs of an investigator

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CTSC Core Services

Customized Access to Patients/Samples

- Access to HIV-infected patients or persons at high risk for HIV
- Biological specimens with pre-specified clinical characteristics
- Specimens from HIV-negative volunteers, to serve as study controls

Facilitate Recruitment and Outreach – Custom Cohorts

Identify and establish collaborations with:

- Patient advocacy groups
- Community advisory boards
- Other organizations that could aid in implementation of clinical research

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CTSC Core Services

HIV Data Registry
Comprehensive adult HIV patient database containing information from all aspects of an HIV patient's medical history:

- Demographics
- Lab results, medical visits, diagnoses, medication history,
- Hospitalizations, immunizations and allergies

These data are available to any investigator pursuing HIV/AIDS research.

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CTSC Core Services

Integration with Other Institutional Resources
Identify, leverage, and integrate institutional resources that encourage/enhance clinical and translational research:

- Integrate resources from other CFAR Cores
- Identify and integrate resources from within URMC
- Identify and facilitate expert consultations or collaborations
- Facilitate access to national CFAR resources

NEW...

- More structured assistance with international research
- CFAR review of grants for external funding

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CTSC International

International Collaborations
The CFAR will provide support to UR investigators whose research involves international studies in resource-limited settings.

This support will include regulatory guidance and advice on best practices, as well as assistance with necessary paperwork/grants management requirements

CFAR Supported Projects:
David Adler – South Africa
Nomvuyo Mahlangu – South Africa
Karen Middelkoop – South Africa
Tinashe Mudzviti – Zimbabwe
Amina Alio – South Africa
Orlando Harris – Jamaica



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CTSC Core Funding

CTSC Funding Opportunities...

- National CFAR supplement grants (internally and externally competitive)
- Internal UR-CFAR pilot RFAs (internally competitive)
- CFAR Mini-grants (administrative review)

All are designed to facilitate subsequent NIH grant preparation and funding

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CTSC Core Events

CTSC Symposium – October 2013...

- Program of speakers including
 - CTSC administration describing core services
 - New investigators benefiting from core services
- Posters from CTSC and other cores, services and programs
- Networking lunch
- Attended by 80-100 participants

CTSC & Development Networking Event – Planned for September 2014...

- Planned event to occur semi-annually
- Brief presentations by new and experienced CFAR members
- Small-group networking focused on increasing collaboration, innovation, funding opportunities, and mentoring

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Basic Science Core

Sanjay Maggirwar, Director

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Basic Science Core Mission

- Enhancing basic and laboratory-based HIV/AIDS research by broadening research capabilities and promoting collaboration
 - Access to cutting-edge instrumentation & technologies
 - Support, education and training to enable efficient use of resources
 - Foster new developments in HIV/AIDS and HIV-related research

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Basic Science Core Virology, Immunology, & Molecular Biology

NEW! FPLC resource (AKTA Pure Chromatography System)

- Purification of proteins, peptides and nucleic acids

Applications:

- Studies of small molecule binding to RNA (Mathews, Miller, Turner labs)
- Purification of HIV-1 RNA for structural studies (Wedekind lab)
- Purification of nucleic acid/protein and protein/protein complexes that include (in various permutations) HIV-1 Vif, APOBEC-3G and viral RNA or DNA (Smith, Wedekind labs)

HIV/AIDS Researchers eligible for discounts

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Basic Science Core Virology, Immunology, & Molecular Biology

Customized Protein Production

Produces, purifies and characterizes biologically active macromolecules (e.g. HIV-1 Env oligomers)

- Recombinant oligomeric HIV-1 gp140 (produced in human cells)
- Monoclonal Antibodies (produced by transient DNA transfection of 293 cells)
- His-tagged recombinant RT (produced in E. coli)
- Custom proteins of interest, produced as His-tagged molecules in E. coli

Applications:

- Studying Env-specific antibodies and B cell responses to Env (James Kobie)

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Basic Science Core Virology, Immunology, & Molecular Biology

High-throughput screening technology

Low cost access to: Envision high throughput plate reader, a Janus dual-arm liquid handling robot, and a Flexdrop plate filler.

Applications:

- Screen relatively small libraries to obtain preliminary data for grant proposals (Spectrum collection of 2000 drugs and natural products; Chembridge Diversity set of 50,000 diverse drug-like small molecules)
- Screen larger libraries for identification of leads for therapeutics
- Identification of novel molecules that can be used to perturb biological systems
- Identify small molecules that can selectively bind defined RNA structures/ targets

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Basic Science Core Chemical and Structural Biology

Temple University's Moulder Center

Resources:

- Access to medicinal chemistry talents, instrumentation and software
- Early phase SAR analysis; ADME; and PK studies
- Commitment of \$500K for pilot awards for early phase drug development (including target identification, early-phase HTS, initial SAR)

Applications:

- To explore innovative therapeutic approaches and targets.

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Basic Science Core Chemical and Structural Biology

Structural Biology Facility

Resources:

- Biacore T100 surface plasmon resonance (SPR) instrument
- Mosquito™ liquid handling robot (TTP LabTech)
- Bruker AXS X8 Prospector
- Technical assistance: training and experimental design and data interpretation

Applications:

- Support & quantitative analysis of biomolecular interactions, and determination of macromolecular structures by X-ray crystallography
 - Screening of proteins, DNA, RNA or complexes in a high-throughput sparse matrix format to set up nanoliter crystallization trials in a low volume, 96-well format
 - Once crystallization conditions identified, support is provided for collection of a complete X-ray diffraction data set on crystals

HIV/AIDS Researchers eligible for discounts

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Basic Science Core Flow Cytometry

Amnis ImageStreamX
Hybrid fluorescent microscope/flow cytometer

Applications:

- Quantitative visualization of platelet-monocyte complexes in the blood of persons living with HIV
 - potential marker for systemic inflammation (Dr. Maggirwar)
- Examination of transcription factor activation, by monitoring the nuclear translocation of NFκB subunits

CyTOF
Hybrid atomic mass spectroscopy/flow cytometer

Applications:

- Phenotypic and functional profiling of the signaling, cytokine, apoptotic and cell cycle-related responses in cells from normal and disease states

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Basic Science Core High-Throughput Sequencing

Illumina HiSeq2500 & MiSeq Sequencers

Applications:

- Conduct unbiased assessment of possible "off-target" effects of novel small molecules that target viral RNA structures
- Examine HIV-1 genomic mutation frequencies in different host cells, and under conditions where HIV-1 reverse transcriptase mis-incorporates ribonucleotides (as was shown to occur in monocyte-derived macrophages by Baek Kim)
- Study transcriptional profile of fat biopsies collected from central adipose tissue, in order to examine how central adiposity contributes to frailty in HIV-infected older adults
- In-depth examination of the transcriptional effects of candidate neuroprotective agents on microglia and macrophages, in order to better understand how they protect against neuroinflammation

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Basic Sciences Core Education and Support

Training

- Seminars
- Posters and formal training sessions
- Visits to individual faculty labs and supported Scientific Working Groups

Voucher Program
CFAR offers funding vouchers for direct application to instrumentation that best suits research needs. Vouchers are competitively awarded and can provide up to \$4,000 in user fees.

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Basic Sciences Core Future Plans (Selected)

Comprehensive High Throughput Screening Resource (C-HTSR)

- CFAR supporting a technician to run this for 2 years
- Leveraged >\$400k in new equipment and resources (Celigo high-content imaging system; robotic RNAi screening platform; genome-wide RNAi library)
- Resource to start operation in fall 2014

Protein Production Core

- Considering an expansion to produce HIV-1 Tat

Education & Training

- Continue seminars on new tools/technologies

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Basic Science Core

Key Contacts:

Sanjay Maggirwar, Core Director
Carrie Dykes, Associate Core Director
Jennifer Lynch, Program Administrator

Website
<http://www.urmc.rochester.edu/center-for-aids-research/services-cores/basic-sciences.aspx>

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Biostatistics, Bioinformatics and Computational Biology Core

Hulin Wu, PhD, Director
Dean's Professor of Biostatistics
and Computational Biology

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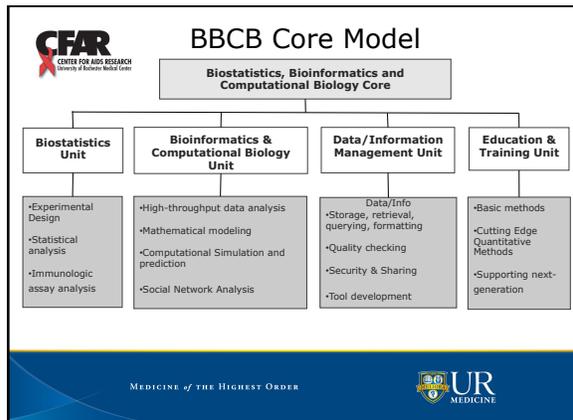
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BBCB Core Mission

- To provide standard and novel statistical, bioinformatics and computational biology support to HIV/AIDS investigators
- Support and collaborate with Investigators
 - Grant proposal
 - Study design
 - Manuscript/abstract preparation
- Provide training
 - Seminars
 - Hands-on lab specific training and consultation

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Biostatistics Unit Service

- Seeks to support and collaborate with HIV/AIDS investigators in basic science, clinical studies and population research:
 - Grant proposal preparation
 - Study design: sample size calculations and power justifications
 - Data analysis for publications

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Bioinformatics and Computational Biology Unit

- Use bioinformatics techniques, systems biology approaches and mathematical or computational modeling for
 - HIV/AIDS research
 - To support and collaborate with HIV/AIDS investigators in basic science, clinical studies and population research

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Bioinformatics and Computational Biology Unit

- Unit Member Expertise:
 - High-throughput "-omics" data processing and analysis
 - Pathway modeling, cellular signaling and regulatory network modeling
 - PK/PD modeling
 - HIV viral dynamics and fitness modeling
 - AIDS epidemics modeling

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Data and Information Management Unit

- Lab, clinical and translational data management support
 - Specimen management and tracking
 - Lab assay data
 - Clinical data
 - High-throughput "-omics" data
 - Documentation and protocol
- Data sharing and dissemination to meet NIH requirements

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Education & Training Unit

- Promote Core services and efficient use of BBCB Core resources
- Provide basic training in biostatistics, bioinformatics, and computational biology to biomedical investigators
- Lab visits to do hands-on lab-specific training and promotion

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BBCB Core Service Policy

- Provide free services for HIV/AIDS related grant preparation
- Provide free services for CFAR pilot awards
- Provide 10 hours of free services for preliminary data analyses and other services for HIV/AIDS grant preparation
- Provide fee-for-services for other requirements

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BBCB Core Future Plans (Selected)

Targeted Support for Early Stage Investigators

- Jian Zhu – Hongyu Miao to continue to support studies of gene interaction networks relevant to HIV-1 latency and reactivation; new pilot award made available outside the CFAR to facilitate this
- Krupa Shah – extensive assistance with statistical & data management support

New Methodology Development

- E.g., Imaging – quantitation of cerebral vasculature

Education & Training

- Continue outreach & individual lab visits/consultations

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BBCB Core

Key Contacts:

Hulin Wu, PhD, Director
Hongyu Miao, PhD, Associate Director
Joseph Guido, MS, Core Coordinator

Website
<http://www.urmc.rochester.edu/center-for-aids-research/services-cores/biomathematical-modeling-biostatistics-bioinformat.aspx>

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Strategic Planning

Steve Dewhurst, CFAR PI

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CFAR Mission

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- Establish a distinctive scientific identity, placing the UR at the forefront of HIV/AIDS research

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Community Building: Creating a scientific home for UR HIV/AIDS researchers

Activity	Rank	Score
Host Scientific Symposia	1=	2.21
Support HIV/AIDS Seminars	1=	2.25
Coordinate Scientific Retreats	1=	2.42
Disseminate HIV/AIDS Research Community News	1=	2.42

Survey Response Rate: ~30%

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Community Building: Suggestions & Responses (1)

Comment: "The CFAR symposium last October was fantastic. Great way to learn what was going on and to network with HIV researchers at UR. The lunch (with assigned seating) was particularly valuable for networking."

Response: CFAR hosting f/u **event on innovative HIV-related behavioral, prevention** and treatment as prevention research occurring campus-wide. Goals: learn about work being done by colleagues; identify collaborations, mentors, grant opportunities; match CFAR services with needs.

- Prelim RSVP sent 6/5/14; **tentative date: 9/19**

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Community Building: Suggestions & Responses (2)

Comment: "Vast majority of lectures are basic science. Could invite more behavioral researcher speakers."

Response: Will solicit a broader slate of seminar speakers.

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Promoting Collaboration & Innovation

Activity	Rank	Score
Pilot Award Program	1	1.67
Vouchers (for new technologies)	3=	3.13
Microgrants	3=	3.00
Actively facilitate collaboration	2	2.33
Develop new SWGs/pre-SWGs	3=	3.04

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Improving our Pilot Award Program

Activity	Rank	Score
Increase funding per award	1=	2.08
Increase frequency of RFAs	1=	2.13
Increase lead time to respond to RFAs	1=	2.29
Improve application review feedback	2	2.83

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Collaboration and Innovation: Suggestions & Responses

Survey Responses:

- Overall Activities:** Need to better promote our microgrant programs; will place high priority on events that promote collaboration (working with Cores, SWGs)
- Pilot Program:** Will explore offering more frequent or larger RFAs (likely cannot do both); will extend RFA lead time

Comments:

- Major suggestion (2 comments): Consider mandating form of collaboration in some future RFAs

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CFAR Supporting Faculty Mentoring & Career Development

Activity	Rank	Score
Provide grant reviews for planned proposals	1=	1.88
Facilitate multidisciplinary mentoring	2	2.46
Offer formal mentoring curriculum	3	3.33
Provide pilot awards for new, ESI faculty	1=	1.92

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CFAR Mentoring and Career Development: Suggestions & Responses

Survey Responses:

- **Grant review service:** Must better promote this service; continue to refine; *working well for supplement submissions.*
- **Pilot awards:** Target some RFAs to new/ESI faculty.

Comments:

- "Let junior investigators know its available let them know of past successes where it helped get funding."
- "Need behavioral research mentors who could meet on regular basis as a group with junior faculty." -> **new service?**
- "Mock review study sections" -> **new service?**

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CFAR Other Comments & Responses

Comments:

- "The NIH want us to have more human subjects training and all the training now seems to be for the study coordinators- we need more for the PI!"

Responses:

- New RSRB guidance documents are being developed; ensure CFAR investigators have an early opportunity to comment before they are rolled out

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Scientific Identity & Planning for Future SWGs

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CFAR Scientific Identity: Future SWGs?

Survey Responses:

- Behavioral working group, prevention working group
- HIV & trauma working group
- HIV and cardiovascular biology
- Modulation of Host Pathways
- Increased focus on behavioral research
- Health services research, community engaged research
- Cardiovascular
- Drug discovery and Proof of Concept

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CFAR VAW-HIV WG Report 09/2013

Five core objectives for action:

- 1 Improve health and wellness for women by screening for IPV and HIV;
- 2 Improve outcomes for women in HIV care by addressing violence and trauma;
- 3 Address certain contributing factors that increase the risk of violence for women and girls living with HIV;
- 4 Expand public outreach, education, and prevention efforts regarding HIV and violence against women and girls; and
- 5 **Support research to understand the scope of the intersection of HIV/AIDS and violence against women and girls, and develop effective interventions.**

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Trauma & HIV WG?

- Several CFAR faculty already work in this area; focus is relevant to their study populations (e.g., MSM, IDU, HIV+, international populations).
- Near critical mass (13 faculty; multiple K, R awards)
- Could bring in others at UR who work on trauma (e.g., Nancy Talbot, Kate Cerulli in Psychiatry; Mt. Hope Family Center)
- Trauma impacts numerous physiologic systems, including neurologic and immunologic systems. Potential for interdisciplinary collaborations.
- NIH appears interested in this area: (i) recent CFAR supplement topics, (ii) VAW-HIV federal working group.

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Response

Explore “Behavior and Prevention” or “HIV and Trauma” pre-SWG

- Would improve mentoring of junior behavioral researchers.
- Aligns w. plans of CTS Core for networking event in the fall.
- Promote new collaborations by expanding this event to include neuroscientists, immunologists OR by hosting a related brain-storming/speed dating event.

Explore “Optics and Imaging” pre-SWG

- Remains a major, largely untapped opportunity

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International Programs & Collaborations

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International Programs: Landscape & History

History (DCFAR):

- Focus on South Africa (UCT, U. Wits); led to K23 for D. Adler
- *DCFAR advisors recommended to place emphasis on our internal investigators & collaborations that benefit them.*

Current Landscape (selected):

- NIH funded: Dave Adler - South Africa (*HPV K23, Yr5*); Amina Alio - SA (*CFAR pilot, effect of religion on behavior*)
- Not NIH funded: Jim McMahan - Estonia & Vietnam (*HIV prev. & behavioral research*)
- Affiliate: Gene Morse (UB) - Zimbabwe (*D43 in pharmacology*)

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International Programs: Recent Changes & Opportunities

Recent recruitments:

- 2013: Gretchen Birbeck, Mike Potchan - Malawi, Zambia. *Focus: Cerebral malaria and pediatric epilepsy (R01s).*
- 2014: LaRon Nelson (SON) – Ghana. *Focus: Prevention among MSM (KAPPA: Kumasi & Accra Project to Prevent AIDS)*

Recent supplements:

- 2013: Tinashe Mudzviti – Zimbabwe (w G. Morse, S Dewhurst)
- 2014 (pndg): Izukanji Sikazwe – Zambia (w G Birbeck)

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International Programs: Question

Steady as we go (supporting role) or change (actively promoting)?

- Current strategy: Primary emphasis on meeting needs of UR faculty, and *supporting* selective international collaborations that benefit their research programs, rather than *actively promoting*
- *Has implications for pilot programs, outreach*

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Inter-CFAR Working Groups

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Defining the UR CFAR's Role in Inter-CFAR Working Groups

Potential New Inter-CFAR WGs:

- **Non-Human Primate WG:** Build bridge to NPRCs; promote ESI w 3-year cohorts of mentorships. DAIDS may have funds in current FY (this summer). *Concerns: Muted enthusiasm of CFAR program; tied to modest UR expertise in NHP research.*
- **Dissemination and Implementation Research:** UR has strong track of engaging the local community and in provider education. *Can we extend to D&I of prevention and behavioral interventions, therapeutics; disparities research?*
- **CAB Support / Community Participation:** Promote best practises; develop training modules; facilitate health literacy. ⁶⁸

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National Role: Question

Thoughts/Recommendations?

- NHP/ESI WG (w. NPRCs)?
- Dissemination & Implementation WG?
- Community Participation/CAB Support WG?
- *Wait and see?*

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