

**Florida Biomedical Research Advisory Council
(Council)**

**November 16, 2009
8:30 a.m. - 5:00 p.m.**

**Meeting Minutes
Strategic Planning Retreat – Day 1**

**Renaissance Orlando Hotel
at Sea World
6677 Sea Harbor Drive
Orlando, FL 32821**

Council Members Present:

Dr. Veena Antony
Dr. Richard Bookman, Chair
Dr. Randal Henderson
Mr. Paul Hull for Dr. Sigurd Normann
Mr. Albert Latimer
Dr. Mary Lou Sole (via conference call)
Dr. Herbert Weissbach, Vice-Chair

Council Members Absent:

Dr. Myra Hurt
Dr. Edith Perez
Dr. Penny Ralston

Program Staff Members Present:

Ms. Sherrie Hajek – DOH, OPHR
Ms. Stephanie Jackson – DOH, OPHR
Dr. Susan Phillips – DOH, OPHR
Ms. Peggy Shults – Lytmos Group
Mr. Chuck Wells – DOH, OPHR

Discussion Moderator:

Ms. Jill Altshuler, AltshulerGray, Inc.

Guests in Attendance:

Mr. Christopher Streeter, AltshulerGray, Inc.

I. Welcome - Retreat goals, expectations

Dr. Richard Bookman welcomed everyone. This is the third BRAC strategic planning retreat over the program history, this time triggered by availability of additional resources for program. It was important that we sought outside strategic planning expertise and facilitation and thus yielded the floor to Ms. Jill Altshuler, who described the goals for the next two days and sought input and consensus from council members.

- **Goals**
 - Set a course for best use of a relatively stable increased funding base
 - Thoughtful reconsideration of how best to meet statutory goals
 - Analysis of how we've been doing to date
 - Sharpen program focus – hone in on what we want programs to do.
 - Define identifiable milestones that demonstrate our commitment to research enterprise, legislators, and to people of FL who expect us to improve health and welfare in the state.
- Should think bigger than just grant mechanisms – what could we do for grantees that would help them be successful and help them achieve goals of program.
- At end of year, would like to compare what we've done to our statutory. Demonstrate that we've addressed those.
- FL recently awarded SSTI
- Timeline – new program ideas could first be implemented in 2011-2012

II. Internal context review

a) Investments and return to date

Statutory goals

- Though other non-tobacco / non-cancer diseases are a concern in FL, our success and longevity tied to our specific charges.
 - Distinguishing feature that our program, unlike other states' tobacco-funded initiatives, focuses on tobacco research, particularly disease pathogenesis.

Investment to date

- Volume of IIR applications when we had mechanism was substantial (~200+).
- Tracking dimensions for awarded grants
 - Should definitely be tracking our funding activities more uniformly
 - Now is the time to update these dimensions
 - “Messiness” of data is an end product of the type of mechanisms we offer. If mechanisms don't target specific research types, you'll get the multiple classifications per grant.
 - Look into NIH's classification scheme, RCDC.
- Success rates
 - When drawing the payline, we've put emphasis on looking at the merit score rather than a percentile ranking – a good system thus far
 - Reasonably confident that at 35-40% payline, we're funding the best research.
 - Will need to expand the pool via new mechanisms to distribute increased funds and still maintain high quality of science

Benchmarks

- Need metrics that help us benchmark our progress against NIH / others

b) Progress toward statutory goals

- BC goals are on a completely different scale – far more targeted than King.
- Staff surprised council feels good about increase in state's per capita research funding. We're still ranked in bottom 40 of NIH per-capita though we did move up one rank. Also surprised that expanding foundation of biomedical knowledge isn't all green.
- Those items council highlighted as showing least improvements parallel those areas Lytmos has most trouble highlighting in annual reports
- # of jobs / post docs / lab personnel used as metric for economic activity

III. External context review

a) State political and funding trends

Legislative climate

- Paul distributed one-page draft summary of King and BC legislative language for upcoming session – eliminates sunset and authorizes in perpetuity.
 - New draft legislation does allow for growing beyond research granting process (e.g. infrastructure, recruitment)
 - Committee members encouraged to give Paul feedback before 12/1 legislative session
- Budget deficit heading into 2010 is \$2.7B.
- Tobacco surcharge revenue estimate will be revised Thursday morning. Though there was a revenue drop immediately after tax went into effect, funding will likely still be near \$50M.

Life science industry

- Life sciences industry continues to have targeted commitment from Life Sciences FL. # of businesses interested in support for expansion / relocation is higher this year than last
- In previous years, had up to \$250M in innovation funding – that fund is gone. Another \$50M in Governor's fund went down to \$13M last year.

Loss of talented investigators

- Large departments are being decimated. Desperate attempt to keep people in FL.

Summary

- It's business as usual – will probably be legislative changes each year, despite efforts to create a more stable platform.
- Should plan for long funding horizon but be aware that there's risk in future years.
- State research institutes need to be aligned / not fighting over same pie

b) National political and funding trends

- Lots of reasons for concern about national scene.
- NIH continues to operate in boom and bust cycles (e.g. ARRA funds)
- Overall economy and federal budget suggests it will be difficult to see significant increases in NIH budget
- Healthcare reform can only serve to decrease operating margins of Academic Health Centers (AHCs)
- Individual investigators getting lost at the NIH level
- Council has been highly responsive to national developments
- Under current administration, looks like significant amounts of clinical, dissemination, CER may be funded through non-NIH mechanisms (e.g. CDC and Office of the Secretary may have significant funds in next 4-5 years).
 - Should make sure our investigators are competitive for this research.

c) Scientific trends: highlights from calls

- A series of PowerPoint slides were reviewed depicting the highlights from the three conference calls conducted in advance of the retreat.

IV. Implications of Internal / External Scan: SWOT

Strengths

- Support for new PIs
- Flexible/responsive with new mechanisms
- Reputation for fairness/peer review
- Reputation for funding best science
- Adherence to statute
- Very efficient/Lytmos
- Strong support from stakeholders
- Strong base of PIs
- Provide funding to broad institutional base

Weaknesses

- Some PIs complain about process, reporting requirements, closed review process
- Peer review does not allow reviewer discussion
- Can't definitively track follow-on NIH/ROI – benchmarks vs. other places
- Not reaching all groups who could apply for funding (e.g., nurses)
- Marketing – but don't have money to spend on it
- Population not well aware of success of programs
- Limited interest in tech transfer program thus far
- Can't track types of research we fund
- Limited progress on BC goals – especially clinical trials and disparities
- Blind process does not ensure we fund specific priorities
- Have not prioritized our research needs

Opportunities

- Network of funded PIs
- Create new models of innovation – leapfrog with innovative, high risk research
- Work with Institute for Commercialization of Public Research
- Open Innovation / incentivize right behaviors – “golden rule”: we have the gold!
- Create statewide CTSA network
- Better publicize funding opportunities beyond MDs and basic scientists
- Network of county health departments
- Mobilize our customer base
- Encourage even more institutional / multidisciplinary collaboration
- Alignment with emerging national priorities – e.g., personalized medicine
- Be more like venture philanthropists – proactive management of translation
- Opportunities in Florida based on population – e.g., disparities

Threats

- Uncertain funding
- Declining researcher population – its “too hard”
- Other states hiring PIs
- Basic research being de-emphasized
- Institutional self-interest undermining our state goals
- Rule-making requirement can slow us down

V. Optimizing Our Research Funding

a) Optimizing our research portfolio

Mix of grants

What's the optimal mix of grant types? What are ways to think about this mix?

- Find ways to prioritize more “important” topics – those that will have the greatest impact (e.g. in disease areas)
- Focus / prioritize King dollars (perhaps by rephrasing King goals) to non-cancer tobacco-related disease since BC is specifically devoted to cancer?
- Define better tracking methods to track grant types along the various dimensions of disease, stage of research, etc. Going forward, would help both decision making process and marketing of program.

Council polled on grant mix priorities. Results below.

- Important to remember that raising these issues is not a matter of either / or. It's about balancing the portfolio, particularly by adding to what's already being done.

| | Any | Targeted | Basic | Clinical / translational | Public health | Individual | Team |
|-------|-----|----------|-------|--------------------------|---------------|------------|------|
| BRAC | 72% | 28% | 39% | 47% | 14% | 64% | 36% |
| Staff | 25% | 75% | 21% | 42% | 38% | 42% | 58% |
| Total | 53% | 47% | 32% | 45% | 23% | 55% | 45% |

Discussion of poll results

- Staff tends to focus on statutory wording of “prevention, treatment, diagnosis, cure” leading to a very patient-oriented way of approaching programs. Feel these dimensions particularly resonate with legislators.
 - Over what time period can we reasonably expect these outcomes?
 - Early emphasis on people/program/infrastructure is what will yield results.
 - War on cancer perfect example of how focusing too early on “translation” can lead to failure.
 - Need hard biology to see results
- How to avoid diluting research over many disease / research types?
 - For UNC, UCRF found balance between top-down big bets and bottom up opportunity fund – getting best of both worlds
- Are there ways to put different research types into different pots – allows funding of best science in each priority category.
 - Another way to think about targeting would be to define a program-wide area of interest and target any application that addresses that issue. Would have to be very careful in choosing this area.
 - Will be able to see some results of targeting via FY10-11 Call for RPG mechanism with a focus in translation and health disparities.

- Alternatively, could define yearly / multi-year focus areas, which will give grants priority. However, grants not in focus areas could still receive funds (e.g. a separate RFA in each of these priority areas).
 - Traditionally, some measure of predictability in terms of funding focus good - people have come to count on this funding.
 - Special emphasis project was one mechanism that briefly addressed this in disparities
 - Good candidates for targeting would be last two BC goals (clinical trial enrollment and disparities)
 - RFP being released on 12/4 targeting clinical/translation/health disparities
- New investigators vs any
 - Consensus that NIR program should remain
 - Additional funds should be made available to more senior investigators
 - o Advantage is more seasoned investigators often do higher-profile science
 - o NIH shown that investigators doing the innovative science are actually older

Quality of grants

- How do we ensure that our program design really goes after quality?
 - Peer review
 - Fund projects that are meritorious but are too early to compete for NIH. Would provide incentive for senior investigators to go off in new direction.
 - Perhaps unwise to just issue an “all comers” IIR creating a large pool of undifferentiated proposals.

Competitive renewals

- If we have projects that look really promising, should we stick with them?
 - Big question is after we start our tobacco researchers; will they be able to compete on in the larger arena for themselves? Possible many have to change research focus to find money.
- Hold people accountable to goals they promise to achieve if applying for renewal.

b) Optimizing the funding process

- New grant mechanisms
- Rolling submissions
 - Experiment now on technology transfer mechanism with rolling submission. Are there other types of projects that could do this?
 - Benefit of rolling submission perhaps not worth the extra work
 - Raises issue of having unallocated funds at year’s end (can’t hold over in escrow) or no funds to fund later applications
 - Possible alternative would simply be grant reviews more than once a year with rolling for smaller grants

Peer review process

- Council should have refresher on reviewers / review process
- Currently have respected reputation for a process that ensures no FL-based investigators on review panel.
- Many reviewers review only 1 proposal. Raises issues of calibration across reviews.
- New options for review process

- A two-step process with current system as step one and second review triggered if scores deviate by a certain amount - for second review, separate set with access to first set's comments / scores
- Two-step process in which 3 reviewers score then pass recommendation along to 2 new reviewers who make final decision
- Stop eliminating top and bottom scores. If there's disparity, should go to second review.
- Have reviewers score their own expertise in the review area
- Improve reviewer questionnaire
- Conduct reviewer orientation
- Use relatedness scores / introduce scores for how well an application addresses targeted research areas

c) Optimizing return on investment

Ideas and poll results (BRAC votes / staff votes)

- Conduct grantee conference (2/2)
- Hold translational conference w/ BioFlorida, Florida CURED, Florida Research Consortium... (1/3)
- Have institutional-level conference or region-based conferences of grantees (3/1)
- Have a conference for members of the public (1/0)
- Maximize chances for getting external funding
 - Pre-application peer review for external funding (0/2)
 - Fund faculty mentors directly to assist grantees in application processes (4/0)
 - Require 'webinars' to supplement what NIR grantees get from mentors (1/0)
 - Fund institutions to provide mentors to all grantees (5/1)
- Open innovation / requiring grantees to share materials / tools / data (3/2)
- Work with technology transfer offices to move grantee research along the pipeline (2/1)
- Commercialization grants (e.g. to MBA students) (0/2)
- Focused training grant that brings together science and business (2/1)
- Special rapid turnaround support for post docs for NIR grants (3/1)
- Create virtual community to identify collaborators (1/1)
- Matching service across grantees with related interests across institutions (2/2)

Open Discussion and Closing:

Dr. Bookman thanked everyone for their participation and the meeting was adjourned at 5:00 p.m.

**Florida Biomedical Research Advisory Council
(Council)**

**November 17, 2009
9:00 a.m. - 4:00 p.m.**

**Meeting Minutes – DRAFT
Strategic Planning Retreat – Day 2**

**Renaissance Orlando Hotel
at Sea World
6677 Sea Harbor Drive
Orlando, FL 32821**

Council Members Present:

Dr. Veena Antony
Dr. Richard Bookman, Chair
Dr. Randal Henderson
Mr. Albert Latimer
Mr. Paul Hull for Dr. Sigurd Normann
Dr. Edith Perez
Dr. Penny Ralston
Dr. Herbert Weissbach, Vice-Chair

Council Members Absent:

Dr. Myra Hurt
Dr. Mary Lou Sole

Program Staff Members Present:

Ms. Sherrie Hajek – DOH, OPHR
Ms. Stephanie Jackson – DOH, OPHR
Dr. Susan Phillips – DOH, OPHR
Ms. Peggy Shults – Lytmos Group
Mr. Chuck Wells – DOH, OPHR

Discussion Moderator:

Ms. Jill Altshuler, AltshulerGray, Inc.

Guests in Attendance:

Mr. Christopher Streeter, AltshulerGray, Inc.

Dr. Bookman called the meeting to order at 9:00 a.m. and turned the floor over to Ms. Jill Altshuler.

VII. Opportunities Beyond Direct Research Funding

a) Brainstorming “Wishes” (BRAC votes / staff votes)

These are pie-in-the-sky wishes. They will be used to explore possible directions for the next five years.

- I wish we could convince Florida how important this is so there was no threat of losing money (3/1)
- I wish we could get the best minds on a particular research topic from across the state (2/2)
- I wish we could fund the most innovative out-of-box research (3/1)
- I wish we could provide resources to overcome translational blocks – Florida Institute for Translational Research Innovation... a state-wide CTSA consortium (4/2)
- I wish we could be more focused so that we could have better metrics (2/1)
- I wish we could improve timeliness of NIR to better support recruiting (3/0)
- I wish we had infrastructure that could help increase enrollment in clinical trials/I wish we could seriously take on challenge of increasing enrollment in clinical trials (9/1)
- I wish Florida research were more visible with internationally-known scientists – bring stars like Texas did, plus their teams (4/0)
- I wish we could find cure for cancer in Florida (1/0)
- I wish we could provide non-research grants to support research in Florida (2/5)
- I wish we could rollover monies without worrying we might lose it (0/1)

- I wish we could identify ways to foster cooperation (3/1)
- I wish we could involve community health care providers more in research (2/2)
- I wish in 10 yrs some recognition that we are “the place” for some area of research (3/0)
- I wish we could harness synergies of our pool of researchers (2/5)
- I wish we could use/leverage researchers by restricting grants to past grantees and forcing them to work together (3/3)
- I wish we could require new grantees to collaborate with past grantees (1/0)
- I wish we were best at addressing disparities (7/3)
- I wish we could have more control over how we achieve our mission like a private foundation (2/1)
- I wish Florida had 4% of NIH grants (2/0)
- I wish we could establish centers of excellence in tobacco-related diseases across Florida – bring in big names as anchor tenants and/or smaller scale recruits (3/2)
- I wish we could provide transition grants to keep grantees doing tobacco-related research and at the institution. Pre-NIR grant, like K99/R00 (1/2)
- I wish we could support MD/PhD programs (2/0)
- I wish we had mechanisms to support feedback from bench to bedside and back to bench (1/1)
- I wish BRAC could better tap all smart people in the state to solve our goals – e.g., via ad hoc task forces (1/0)

b) Breakout sessions

- The BRAC and staff split up into three breakout groups to discuss three possible themes. These were not necessarily the themes with the greatest votes. These are exercises to help Council members consider new directions / mechanisms.
 1. How to address the challenge of clinical trial enrollment -- via infrastructure or otherwise? – Paul Hull, Randy Henderson, Susan Phillips, Peggy Shults
 2. How to address the challenge of health disparities via our research? – Al Latimer, Richard Bookman, Penny Ralston, Chuck Wells, Stephanie Jackson
 3. How to recruit international research leaders so that FL can become “the place” for a particular area of tobacco-related/cancer research? – Herb Weissbach, Veena Antony, Edith Perez, Sherrie Hajek, Jill Altshuler

c) Breakout readouts

Team 1: Clinical Trial Enrollment

Four goals specified within second goal of Bankhead Coley

- Enrollment
- Public/private education
- Tools to oncologists/patients to identify
- Opportunities for states AMCs to collaborate with community-based oncologists

Challenges

- Silos, people protective of patients
- Population lives away from academic centers – 80% treated in community

- Patients have misconceptions about clinical trials

How to pursue this

- Funding for database matching and education – yellow pages, help match patient to the trial, educate patients upfront about what clinical trials are all about – educating patients and MDs
- Establish statewide cancer trial clinical trial network – collaboration between academic centers and community centers to conduct trials. Make more options available in the community
- Telemedicine for consults/ second opinion for patients

Results

- Impact on recruits, disparate participation, completion of trials

Feasibility

- Convene stakeholders to solicit input
- Look at other state networks: GA, TX, NC

Team 2: Disparities

Idea entails

- What kind of disparities: cultural and ethnic
- Genetics/biological, nature/nurture
- Access

Why do it

- Stated B-C goal
- Higher minority disease burden
- Healthy People 2010 goals written into statute
- Increased federal funding for disparities
- Fits with trend towards personalized medicine
- Increased partnerships with minority serving institutions

How we would pursue

- Center grants
- Educate BRAC on breadth of disparities
- Communicating with community
- Convene experts who can talk to us – an Advisory Council to Advisory Council
- Workforce issue – if we can attract minorities into sciences likely to ask questions relevant to backgrounds
- Meet with newest DOH Director of the Office of Minority Health (Dr. Turner) to identify mutual goals – January BRAC meeting
- BRAC needs information in order to design some tuned mechanisms!

Challenges

- Attitudes regarding genetics and participation in clinical research
- How to ensure community engagement

How to achieve

- Learn more

- Build partnerships
- Design mechanisms

Group 3: Recruit Star Faculty to Florida

The issue: how to help increase the visibility and quality of research in state of Florida

Florida is lagging behind

- NIH funding
- Only three National Academy of Science members in entire state who are active in biomedical research
- No clear plan at state level except for what Jeb Bush did with Scripps and Max Planck.

Two possible approaches

- 1) Attract one internationally known scientist to FL per year. An institution can seek this funding if they have identified an absolute star who will fit into and transform an area of tobacco or cancer-related research at their institution, and they are seeking matching funds. They may be seeking start up funds to bring this faculty member and his/her team, with institution taking responsibility for salary. Will cost \$5M or greater. Could also leverage other organizations/foundations for funding. Will attract tremendous publicity, and notice from other scientists.

How to measure success? Number of NAS, IOM members, increased funding (faculty will bring existing NIH funding, etc.), recruitment of others

Issues

- How to put out proposal for this, how will be evaluated, will be challenging to work out. Will not involve putting out an ad, but an institution being able to say, we want this particular person. “What’s it going to take to bring you here?”
 - Money has to go to research, not recruitment
 - Would have to be brought in from out of state
 - Could stipulate that only one application per institution per year; can’t reapply for 2-3 years if get it
- 2) Give existing Florida scientists sums of money to establish centers of excellence
 - Easier to do – centers know who their stars are, can invest and keep
 - Downside – not bringing in fresh blood, doesn’t get publicity
 - Would come with hurdles – how is going to parlay into various areas
 - Publication, citation counts, national recognition (IOM, NAS)
 - Management of talent has to be part of plan

VIII. Improving Metrics and Communications

a) Improving how we track/measure

b) Improving how we communicate with/to stakeholders

Ideas for improved communications

- Annual Report
- Mobilize grantees

- Hire PR firm like GA did? Brand our program
- Targeted communication to institutional stakeholders (“customers”)
- Other key stakeholders: advocacy groups, community groups
- Distribute set of 5 -12 slides to tell the story that we can all use
- Challenge: can’t spend much taxpayer money on this
- “Research Means Hope”
- Office of Research at institutions should get list/press release
- “Big ideas” discussed this afternoon could be big stories
- Website – BRAC would like to see stats on website usage. Get institutional sites to link to our site?
- Get other state agencies to highlight what we do – ensure King/BC is mentioned whenever biotech in state is discussed
- Learn from Scripps re: publicity

IX. Retreat Review

Day 1: Optimizing how we fund research

What we fund

- Maintain investment in basic research, but...
- Increase relative investment in clinical/translational/public health
- Expand beyond new investigators (NIRs)
- Set aside some targeted funding for priority areas

How we solicit and select proposals

- Use TTCP mechanism as experiment for rolling submissions
- Give greater weight to proposals in identified priority areas
- 2-tier peer review/other ways to improve review within of sunshine law
- Better tracking of data to categorize grants and measure impact

How we ensure the greatest return from our investment

- Bring together grantees in particular geographic/topic areas
- Provide support to institutions to mentor grantees to help obtain follow-on funding

Day 2: New ideas for further exploration

Clinical trials networks

- Database matching and education
- Statewide clinical trials network
- Telemedicine for consults

Disparities

- Learn more -- bring in leaders to advise the Council on disparities
- Build partnerships in communities and with other agencies/depts
- Design mechanisms -- genetics, dissemination research

Recruitment/retention of talent

- Recruit “superstars”/teams to FL in tobacco/cancer-related science
- Develop Centers of Excellence in different diseases at different institutions

X. Role of Council Members

Statute description of BRAC responsibilities includes dissemination

- Should we offer dissemination fund for current grantees to apply for – on a just-in-time basis if had research finding we could provide research funding for dissemination
- How to encourage inclusion of King/BC discoveries as practice guidelines are being developed

View DOH as a laboratory – focus on primary care in county health depts. DOH MD could get involved in the practice guidelines. Opportunity to tap into network of county health departments

Other role for BRAC members – marketing

- Have BRAC members man a booth at FL and national meetings... ACS, AHA

XI. Wrap Up/Next Steps

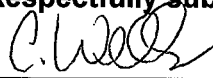
Dr. Bookman – closing remarks

- Tremendous spirit of collaboration, commitment to move the ball forward
- A lot of work to do between now and January meeting
- AltshulerGray will draft strategic plan outline / framework for input and review at January meeting

Open Discussion and Closing:

Dr. Bookman thanked everyone for their participation and the retreat was adjourned at 4:00 p.m.

Respectfully submitted on behalf of Dr. Richard Bookman, Chair

 1-29-10

**Chuck Wells, Assistant Director
Office of Public Health Research**

**Florida Biomedical Research Advisory Council
(Council)**

**November 18, 2009
8:00 a.m. - 12:00 p.m.**

Meeting Minutes

**Renaissance Orlando Hotel
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Council Members Present:
Dr. Veena Antony
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Ms. Stephanie Jackson – DOH, OPHR
Dr. Susan Phillips – DOH, OPHR
Ms. Peggy Shults – Lytmos Group
Mr. Chuck Wells – DOH, OPHR

Guests in Attendance:
Philip Arlen, MD Anderson, Orlando
Riyaz Mahammad, MD Anderson, Orlando
Melissa Kuchma, MD Anderson, Orlando

I. Call to Order & Welcome:

Dr. Bookman called the meeting to order.

II.a. Approval of Minutes:

Minutes of the August 31, 2009, Council meeting were presented. Dr. Weissbach moved that *the minutes be approved as presented*. This motion was seconded and passed unanimously.

III. Projection of Available Funding:

Dr. Phillips reported that, based on actual revenue from the cigarette surcharge for July, August, and September, the projected annual proceeds to the King and Bankhead-Coley Programs are \$24.98 million each. Since it is still early in the fiscal year (FY), she recommended the Program base its funding on 90 percent of the maximum amount. This is an increase from her previous recommendation of 80 percent of the maximum.

The King Program has an additional \$2.2 million from interest on funds set aside in the Lawton Chiles Endowment Fund, and OPHR projects an anticipated surplus in the administrative expense budget. After subtracting funds committed for awards already started in July and administrative funds, roughly \$12.1 million is currently available for making new James & Esther King grants.

The Bankhead-Coley Program received an additional \$358,000 from the Scripps re-investment required under section 288.955(13), *Florida Statutes*. Dr. Phillips also expects a surplus from the administrative expenses budget. After subtracting administrative expenses, the grants started in July, restoration of grant reductions made to FY 2008-2009 grants, and \$500,000 for the McKnight Brain Injury Foundation, the available funding for new Bankhead-Coley grants is approximately \$9.2 million.

Another quarter's data on the cigarette surcharge proceeds will be available in January. Council members agreed to identify fundable but unfunded applications in case more money is available.

IV. King Grant Funding Recommendations:

Ms. Shults described the pool of applications submitted in response to the James & Esther King Program Special Calls: 19 for Florida Research Challenge (RC1) Grants, 8 for Shared

Instrument Grants (SIG), and 2 for Technology Transfer/Commercialization Partnership (TTCP) Grants. (Ms. Shults later corrected the number of TTCP applications to 4 as of November 12th). The total value of all requests was approximately \$17 million. Ms. Shults presented a breakdown of applications by research topic classification, as self-identified by applicants. Seven Florida institutions submitted applications, down from 14 in the spring competition.

Ms. Shults also described the peer review process used to evaluate the applications. A total of 53 peer reviewers from outside Florida assessed the merits of the King applications. She reminded the Council of the evaluation criteria used for each mechanism.

Because funding for the TTCP open competition is based on a predetermined merit threshold, Ms. Shults reported the current status of applications for these grants. Of the four TTCP applications received as of November 12th, one has been funded. This grant's start date is December 1st, and the project leader is Dr. Stuti Dang at the University of Miami. A second award is pending approval by the State Surgeon General. The third application has been administratively disqualified, and the fourth is awaiting clarification regarding potential overlap before undergoing review.

Shared Instrument Grant Conflict of Interest Discussion:

Ms. Shults then prefaced further Council discussion on funding recommendations with a request for Council opinions on policy regarding SIG applications in which a Council member is named as: a) a member of the advisory committee overseeing equipment use, or b) a Principal Investigator on a project that will use the requested equipment. Mr. Wells suggested three potential resolutions in addressing each case: 1) determine that there is no conflict of interest; 2) treat this as a managed conflict of interest issue, recusing affected members during relevant funding discussions; or 3) disqualify the applications. Mr. Wells reminded the Council of applicable statutory language regarding conflict of interest, as well as a 2005 Council resolution, in which the Council self-imposed a tighter restriction: "*Council members may not fill any named role in a grant application for program funds, regardless of remuneration status.*" Some members recalled that the Council's intent at that time extended to prohibiting any consulting, advising, or reviewing specific proposals during preparation. It was clarified that Council members are permitted and encouraged to promote the Programs and the grant mechanisms as a whole, as long as no advantage is extended to a specific applicant. Dr. Phillips said a frequently cited quality of the Program is its purely competitive funding, based on merit, without real or perceived conflict of interest. She cautioned the Council to avoid any appearance that Council members have an unfair advantage in directing and/or receiving awards.

A few Council members pointed out that the position taken in the 2005 Council resolution is detrimental in cases where an active senior investigator at some of Florida's smaller institutions and academic departments is also serving on the Council. All agreed that having leading researchers on the Council is vital to the Program.

Dr. Bookman suggested that, prior to disclosing any peer review scores for the SIGs, Program staff go through the evaluations of each SIG application with a potential conflict and determine whether it is possible to tell whether the role of the named Council member was a significant factor in the assigned merit scores. If so, staff would determine manageable conflicts or disqualifications. Dr. Weissbach moved to *adopt this proposal*. The motion was seconded. During discussion, several Council members expressed concern about possibly introducing more conflict of interest by looking at individual proposals, which is a departure from past practice.

Three guests joined the meeting.

Council members sought clarification regarding the likely influence on the peer review

merit scores of a Council member on the equipment advisory committee or in the role of Principal Investigator for projects demonstrating the need for the instrument. Ms. Shults reiterated the SIG evaluation criteria applied by the peer reviewers, and reported that the only biographical sketches accessible to the peer reviewers were those of the SIG Principal Investigator and the chair of the equipment advisory committee. After further discussion, Dr. Bookman asked for closure on the motion under consideration, and Dr. Weissbach withdrew it.

Dr. Bookman asked for a show of hands from all Council members aware that they had been named in a SIG application. No hands were raised. It was acknowledged that Council members might be named in proposals without their knowledge.

Council members agreed that the 2005 Council resolution should be revisited during the January Council meeting, and that for the purposes of this meeting, the statutory direction should apply. Dr. Weissbach withdrew his motion and Dr. Ralston moved that *all Council members named in any capacity on a SIG application should leave the room for all funding discussions for that mechanism and the overall distribution of funds across mechanisms*. The motion was seconded and passed unanimously.

Ms. Shults presented a funding worksheet containing a list of submitted RC1 and SIG proposals, identified only by application number and ranked according to peer review scientific merit scores. For each proposal, the average tobacco-relatedness score from the Lytmos reviewers was also provided.

During discussion of the RC1 applications, Dr. Bookman reported that in the federal competition, 90 percent of the applications were triaged (not given any scores) and that the overall success rate was approximately 4 percent. In addition, the National Institutes of Health (NIH) describes an impact score of 3.0 on its new rating scale of 1 to 9 as “excellent” and 4.0 as “very good.” Mr. Hull recommended funding all RC1 applications with a tobacco-relatedness score of 3.0 (on a scale of 1.0 to 5.0, with 1.0 being most favorable) or better. Council members agreed to temporarily accept this option as they moved to considering the SIG applications.

At this point, Dr. Bookman was informed that he had been named by an applicant on a SIG application; after yielding the chair to Dr. Weissbach, he left the room.

Ms. Shults reminded the Council that the SIG scientific merit scores were based on a scale of 1.0 to 5.0, with 1.0 being most favorable.

Dr. Sole moved that *the top five SIG applications be funded*. Dr. Weissbach pointed out that there were two more proposals beyond those five with merit scores of 2.2 or better. After requesting clarification from Ms. Shults regarding the tobacco-relatedness scoring used by the reviewers, the Council agreed that the same threshold of 3.0 recommended for the RC1s should be applied to the SIG applications. Dr. Sole modified her motion, that *the top seven SIG applications be funded*. This motion was seconded and passed unanimously.

The Council discussed the fact that the current funding scenario fell short of the total available funds. Rather than compromising the Program’s standards for quality, the Council preferred to consider selecting one or more meritorious applications from the next (FY10-11) competition for funding in the current fiscal year, with the grant(s) to begin June 1st.

The Council agreed to reserve \$1 million for TTCP grants to be awarded in the current fiscal year. Dr. Sole moved that *the earlier RC1 funding recommendation [all RC1 applications with a tobacco-relatedness score of 3.0 or better] be adopted*. The motion was seconded and passed unanimously.

Dr. Bookman rejoined the meeting, and he was informed of the funding recommendations approved in his absence.

V. Bankhead-Coley Grant Funding Recommendations:

Ms. Shults reported that the applications submitted in response to the Bankhead-Coley Special Calls included 19 RC1s, 15 SIGs, and 1 TTCP, as of November 12th, requesting a total of just over \$20 million. Proposals came from six Florida institutions, compared to nine in the first FY 2009-10 competition.

Eighty scientific peer reviewers from outside Florida completed evaluations of these applications.

One Bankhead-Coley TTCP application has been received and reviewed as of November 12th, but it failed to meet the minimum scientific merit-funding threshold.

Ms. Shults presented the funding worksheet containing a list of submitted RC1 and SIG proposals, identified only by application number and ranked according to peer review impact/merit scores. For each proposal, the average cancer-relatedness score from the Lytmos reviewers was also provided, as well as an indicator for those proposals with a strong health disparities emphasis.

Dr. Bookman once again pointed out that an average RC1 score of 3.7 is on the border between NIH's "excellent" and "very good" categories. The Council temporarily reserved money for RC1 proposals with merit scores up to 3.5, as long as the cancer-relatedness score was 3.0 or better.

Dr. Perez left the meeting.

Before discussing the SIG applications, Ms. Shults identified Drs. Hurt and Perez as Council members in named roles on Bankhead-Coley SIG applications, neither of whom was present.

In consideration of the fact that the Bankhead-Coley Program had a lower remaining budget to satisfy a great demand for funding, Dr. Bookman asked Dr. Phillips if it would be possible to move money from the King Program to the Bankhead-Coley Program. Dr. Phillips said that while it may be possible to move some applications from one Program to the other as long as they satisfied Program intent, she was not in favor of that. Before doing so, it would be necessary to consult Department counsel.

Mr. Hull questioned why there appeared to be a relatively few number of applications competing for funding. Council members explained that the nature of these mechanisms severely restricted the number of eligible applications, particularly the RC1s, since they were limited to cancer-related projects (tobacco-related projects for the King Program) that were highly scored in the recent national competition.

Several Council members expressed a preference to fund more RC1s than SIGs due to their greater potential for innovative research. A reserve of \$200,000 was recommended for TTCPs.

Examining different scenarios on the funding worksheet showed that making a 5 percent reduction in RC1s enabled RC1 projects with similar scores to be funded.

Mr. Wells asked the Council to identify unfunded but fundable applications, in the event that additional money becomes available.

Dr. Antony moved that *the Bankhead-Coley Program fund RC1 applications with standard proposal scores of 3.5 or better and cancer-relatedness scores of 3.0 or better at 95 percent of the requested amount, SIG applications with standard proposal scores of 1.5 or better, and that \$200,000 be reserved for TTCPs.*

Dr. Perez rejoined the meeting, only to be informed that she must step out during the remaining funding discussion to avoid a potential conflict of interest. She left the room.

Dr. Sole modified the motion on the floor to add that *if additional money becomes available, priority will be given to SIG applications up to a standard proposal score better than 1.9.* The motion was seconded and carried unanimously.

Dr. Perez was invited back to the meeting.

II.b. Public Comments: Dr. Bookman invited comments from the guests.

Dr. Arlen said that as a currently funded Bankhead-Coley grantee, he was extremely encouraged by the discussion he heard. It was clear to him that the Council and the Department are focused on carrying out the Program mission as intended, funding Florida investigators who are trying hard to compete for federal funding in a difficult game. He agreed that scientific merit should be the determining factor in making awards, and said the importance of the Program is encouraging biomedical research that can be competitive at the national level. He thanked everyone for the process by which the awards are determined.

Dr. Mahammed asked for clarification of the rationale for imposing the tobacco-relatedness requirement for King grants and assessing applications against that requirement. Dr. Bookman explained the Florida statutory requirement. While the Program takes a broad view of tobacco-relatedness, projects that cannot demonstrate a reasonable relationship to tobacco-use do not satisfy the goals of the Program.

Dr. Kuchma inquired whether a project focusing on lung cancer would be considered tobacco-related, and he was told that it would be. Dr. Bookman said the King and Bankhead-Coley Programs are normally equally competitive, and that the significant funding imbalance between the two programs was not the norm. When asked if the same application could be submitted to both programs, he responded that it could not.

VI. Status of FY 2010-11 Calls:

Ms. Shults reported final refinements to certain Calls, including:

- New Investigator Research (NIR) grants – the addition of a minimum 3 percent effort for mentors
- Team Science Program (TSP) grants – a restriction of 20 percent of funds that may be spent outside Florida, and the inclusion of in-kind contributions for the required institutional match

Council members debated whether the 20 percent restriction was too high. Dr. Sole moved that *the maximum percent of funds expended for out-of-state work be set at 10 percent*. The motion was seconded and passed unanimously.

Ms. Shults asked for Council assistance in finalizing the stipend and allowance amounts for the Postdoctoral Research Fellowship (PRF). After a brief discussion, Drs. Antony, Bookman, and Weissbach agreed to provide feedback after the meeting as a subcommittee.

Ms. Shults asked for a recommended minimum effort for the PRF, and the consensus was 75 percent.

Peer reviews for all applications will be conducted using a 1-9 scale, patterned after recent changes introduced by NIH. Lytmos is streamlining the online application to cluster downloadable templates and uploaded sections of the application.

The pre-announcement of the Calls was released on November 16th, and the Calls will open on or around December 1st, with applications due February 12th.

For planning purposes, Council members projected that larger research institutions such as University of Florida and University of Miami may generate 40 to 60 Research Project Grant (RPG) applications and 10 to 20 PRF applications, and smaller institutions can be expected to generate roughly one-fifth of this number.

VII. OPHR Report

Mr. Wells said OPHR now reports to Deputy Secretary Kimberly (Kim) Berfield, and there is a

new Minority Health Deputy Secretary, Dr. Shari Turner. No impact on the Programs is expected.

Mr. Wells reported that six applicants recommended for funding from the regular call did not accept the award as a result of receiving federal funding and none of those accepting awards have relinquished funding.


Mr. Wells informed the Council about the recent national recognition of the King Program by the State Science and Technology Institute (SSTI), with its 2009 award for excellence in technology-based economic development in the category of expanding research infrastructure. He distributed copies of the presentation he and Ms. Hajek made at the SSTI conference. He also noted Dr. Hurt's recent presentation about the King and Bankhead-Coley Programs at the BioFlorida conference.

The American Cancer Society (ACS) will hold a policy summit in Orlando on December 1st, during which the ACS will advocate for the reenactment of the King and Bankhead-Coley programs. Mr. Wells has been invited to present information at this event. Mr. Hull encouraged Council members to attend, if possible.

VIII. Open Discussion and Closing:

Dr. Sole moved that *the meeting be adjourned*. The motion was seconded and approved unanimously. The meeting was adjourned at 11:58 a.m.

Respectfully submitted on behalf of Dr. Richard Bookman, Chair

 1-29-10

Chuck Wells, Assistant Director

Office of Public Health Research