
RECORDED MINUTES
Research Policy Committee

April 14, 2008

3:30 p.m.

PRESENT

Kathleen Campbell, Ph.D., Chair

Sukesh Bhaumik, Ph.D.

Mark Johnson, M.D.

Teresa Liberati, Ph.D., D.V.M.

Mary McAsey, Ph.D.

Paula Mackrides, D.O.

Joseph Milbrandt, Ph.D.

Prema Narayan, Ph.D.

Jodi Huggenvik, Ph.D. (proxy for Peter
Patrylo, Ph.D.)

Louis Premkumar, Ph.D

Greg Brewer, PhD (proxy for Sophia Ran,
Ph.D)

Laura Rogers, M.D.

Don Scott, M.D.

Steven Verhulst, Ph.D.

Ex-Officio Members:

Sandra Puczynski, Ph.D., Director of
Clinical Research Development

Linda Toth, Ph.D., Associate Dean for
Research and Faculty Affairs

ABSENT:

M. Steven Evans, M.D

Ex-Officio Members

Ko Watabe, Ph.D., Chair, Central Research
Committee

The meeting was called to order at 3:30 p.m. by Dr. Campbell.

Approval of Date March 3, 2008 Minutes

Dr. Mary McAsey moved and Dr. Louis Premkumar seconded that the March 03, 2008 minutes be approved as presented with corrections to the previously circulated March minutes to clarify that the Carbondale Faculty were in attendance. The committee voted unanimously to approve the minutes with the corrections.

Announcements:

1. Dr. Campbell will be visiting Carbondale on April 23, 2008. She and Rob Patino, Director of the Technology Transfer Office, will present the Patent and Intellectual Property

Seminar for the Carbondale SIUSOM faculty and then she will meet with the Carbondale RPC members and proxies. As a part of that visit they will also tour the incubator facilities.

2. Dr. Campbell will give RPC update to Executive Committee today. She acknowledged everyone's assistance with the RPC subcommittee work.
3. The Space Allocation Subcommittee has met and approved the final revised documents. The surveys will be sent out after the faculty research surveys have been completed.
4. The faculty research survey has been sent out. Dr. Verhulst will compile the results and present them to the RPC at the May faculty meeting.

Items for Discussion:

I. RPC Subcommittee Chairs for Strategic Plan Tasks:

Dr. Campbell asked each subcommittee to report its assessment of current infrastructure needs for its research area. Dr. Ran was absent but the Basic Science subcommittee members stated that there had been no changes from the previous report presented at the February RPC meeting. Therefore a copy of Dr. Ran's subcommittee's previous report is included at the end of the minutes.

Laura Rogers, M.D. Clinical Research – Dr. Rogers presented her subcommittee's report. Dr. Rogers reported her subcommittee conducted structured interviews and focus group within the various departments. Her report is appended at the end of the minutes.

Teresa Liberati, Ph.D., DVM Translational Research : Dr. Liberati's written report is provided as an addendum at the end of the minutes. Dr. Liberati's subcommittee has had several meetings focusing on prioritization of in-house grant mechanisms, and infrastructure needs at SIU, Carbondale and Springfield.. There is some concern as to whether we have the infrastructure in place to handle bench to bedside translational research without gaps in between. Also the timeline and need for financial support to enhance translational research was discussed.

Steve Verhulst, PhD Humanities and Medical Education Research Subcommittee – Dr. Verhulst presented his report and it is appended at the end of the

minutes. In addition to the items contained in Dr. Verhulst's report some suggestions made at the RPC meeting were considering a PhD program in Medical Education at SIUSOM, the need for a research coordinator to help identify funding opportunities from foundations, a possible behavioral science core, and perhaps a faculty coordinator to match up researchers across departments.

General Discussion: In addition to the above committee reports some general discussion ensued on impediments to research. These discussions included:

- The need for a incentive and salary system that was comprehensive for clinical, research and teaching responsibilities of each faculty member. Currently, clinical faculty may reduce their income if they become involved in research. One option is a completely separate track for full time clinicians.
- It was felt that the promotion and tenure guidelines should be reviewed to better promote and reward research.
- It was also suggested that there be a review of departmental use of overhead money from research grants to ensure that the indirect cost money is used to support research and not other activities.
- Priority should be given to hiring fellowship trained clinical faculty who are more likely to be involved in research.
- Recruitment of new department chairs should focus on those with a history of major research grant funding. A departmental chair without a history of major grant funding for research is unlikely to serve as a successful role model or supervisor for faculty members conducting research in that department.
- It was felt that the Dean and all Department Chairs must clearly specify that research is an essential part of the mission of our faculty members.

II. Prioritization of Internal Funding was presented by each of the subcommittees.

Discussion followed. The consensus of the committee was that:

- Keep the following new awards because they are too new to fully evaluate: Concept Development Award, FAAR and Clinical Scientist Award.
- Retain EAM and CRC grants but consider relative distributions between these regular mechanisms and the Near Miss Awards and potential Bridge Funding Awards.
- Consider collapsing Bridge and Near Miss EAM and CRC grant awards. We need to be sensitive to the fact that Carbondale faculty are ineligible for EAM funds so need to ensure that bridge funding, if developed, is also available to them.
- Some discussion occurred regarding the problems for clinical research funding with current mechanisms.
- It was decided by consensus that prioritizing internal funding mechanisms will be further discussed at the May RPC meeting.

A motion to adjourn was made by Dr. Rogers and seconded by Dr. McAsey. The motion passed unanimously. The meeting was adjourned at 5 PM.

ADDENDUM:

Written Reports of the Subcommittees to address the Strategic Plan:

RPC Clinical Research Subcommittee: Common Themes

Subcommittee members:

Laura Q. Rogers, MD, MPH (Chairman)
 Joe Millbrandt, PhD
 Steve Evans, MD
 Mark Johnson, MD
 Sandy Pucynski, PhD (ad hoc)
 Steve Verhulst, PhD (ad hoc)
 Larry Hughes, PhD (ad hoc)

Introduction: During January, February, and March of 2008, the members of the RPC Clinical Research subcommittee performed structured focus groups sessions with the following SIU Clinical Departments: Surgery, Medicine, Pediatrics, Psychiatry, OB/GYN, Neurology, Neurosurgery, and Family Community Medicine. Detailed notes of comments shared during these sessions are attached. The most frequent “common themes” related to barriers to clinical research and possible solutions for facilitating clinical research that were suggested during the sessions are summarized below.

Barriers:

More frequent

- A “culture” not conducive to research. For example, research activities are not valued or rewarded and, at times, are not well-understood by colleagues and all levels of administration. There are time and financial disincentives for doing research. There is a lack of “investment” in research at an institutional level (e.g., financial, strategic hiring of leaders and faculty, administrative, attitudinal, etc.).
- Lack of time for research that is consistently “protected” from clinical responsibilities.
- Lack of administrative understanding, experience, and structure related to contracting, regulatory support, research compliance, finances, etc. that prevents successfully competing for pharmaceutical sponsored clinical trials.

Less frequent

- Complicated institutional policies and procedures such as that required for SCRIHS.
- A geographically and academically “fractured” campus which results in redundancy and overlap because of poor communication, collaboration, and coordination.
- Lack of support for research such that individuals involved in research feel alone, tired, and frustrated (e.g., lack of funds, inexperienced and/or minimal staff assistance, etc.).
- Lack of interest.
- Lack of funds due to minimal philanthropy and allocation of money away from research (e.g., to hospitals and SIU P&S).
- Lack of fellowship positions.
- Lack of competitive research charges for clinical tests which make clinical research, at times, impossible due to unreasonable cost.

Solutions:

More frequent

- Change the culture from the “top down” and create a system that values and rewards research. The institution should articulate a research vision and commit to a long-term, consistent, and significant investment in clinical research.
- Increase efficiency of faculty research activities by creating a centralized core clinical research center including services such as:

- Research nurses
 - Sample collection, handling, shipping, and storing
 - Staff to identify funding sources and connect potential investigators with clinical trial options
 - Participant recruitment office
 - Faculty development
 - Budget assistance
 - Contracting/legal
 - Grant/manuscript writing, preparation, etc.
 - Statistical support
- Create infrastructure for maintenance of patient databases and tissue/blood banking for research purposes. Such infrastructure should include services such as:
 - Infrastructure for entering, maintaining, and cleaning data
 - Specialty support such as histology, pathology, etc.
 - Epidemiologist
 - Faculty education and “buy-in”
 - Ability to use databases/banking to successfully compete for research support through industry, etc. (i.e., maximizes the benefits of databases/banking)
 - Increase collaboration between basic scientists and clinicians.

Less frequent

- Enhance mentoring.
- Increase efficiency by decreasing redundancy in the system and overlap among required paperwork, etc.
- Hire more faculty interested and experienced in doing research. Retain faculty who show promise or are already successful in doing clinical research.
- Create access to core laboratory services (e.g., identify regional resources, educate faculty, establish a “clearinghouse” so that faculty can identify services with one telephone call to a central office).
- Support faculty who are already successful at doing clinical research or who demonstrate promise of success.
- Establish more MD/PhD programs.

In addition to the above common themes report the Clinical Research Subcommittee prepared the following recommendations to promote medical student and resident research.

Recommendations related to increasing the involvement of medical students and residents in clinical research at SIU School of Medicine:

1. Strengthening clinical research activities at SIU School of Medicine will allow more opportunities for medical students and residents to be involved in patient-oriented research.
2. Ensure that research activities are a worthwhile educational experience for the medical student or resident who is involved.
3. Increase awareness of possible opportunities for involvement through multiple delivery channels.
4. Creatively design ways for the medical student or resident to “make an activity count twice”. Integrating research activities into their other activities will help address barriers related to unpredictable schedules and restricted time frame of availability.

RPC Translational Research Subcommittee Report

Members: Teresa Liberati, DVM, PhD, Kathleen Campbell, PhD, Peter Patrylo, PhD, Paula Mackrides, MD, Louis Premkumar, PhD

This report contains an assessment of current infrastructure needs and suggestions for future development as it pertains to translational research. These notes were used to develop questions for the faculty survey. This is summarized below and followed by an inclusion of the minutes from two meetings of the committee.

Infrastructure Needs at SIU, Carbondale and Springfield Campuses

1. Administrative Core – people who have been on review panels for many years and have expertise in grant preparation. Special office that conducts in-house review prior to submission. Also will help with proper paperwork, forms, etc.

Future Development: This item was placed on the faculty survey. This need would require administrative and monetary support to hire 1-2 individuals initially to support this activity.

2. Office to liaison with biotech companies and major pharmaceuticals for out licensing, R&D, development, etc. Someone who knows how to tap into these resources, keep abreast of company profiles, pipelines, market trends and knows how to handle due-diligence visits.

Future Development: This item was placed on the faculty survey. This need would require administrative and monetary support to hire an individual to support this activity. Other infrastructure needs would likely need to be completed prior to this (i.e. developing greater capabilities to conduct pre-IND studies).

3. Public Relations – individuals to get the information and research out into the mainstream. Group who will take strengths of individual scientists and find venture capitalists to make investments.

Future Development: This need may be able to be met by placing an additional individual in the current PR group with these specific objectives and responsibilities.

4. Statisticians – large need for more PhD level individuals with specialties in basic, clinical and translational research. Could be on both campuses or could share across campuses.

Future Development: This item was placed on the faculty survey. This need would require administrative and monetary support to hire 1-2 individuals initially to support this activity.

5. Technology Advancement Office – individuals whose job it is to go out to clinicians and/or faculty and ask what do you need to do your job better? Solicit ideas and match with faculty working in those areas or capable of developing the idea.

Future Development: This need would require administrative and monetary support to hire 1-2 individuals initially to support this activity.

6. Increased presence of the Patent Office – offer services to help smaller companies and biotechs develop their idea or file for provisional patents if they are working with SIU.

Future Development: This need may be met potentially by the individuals already working in this area or by the addition of 1 individual. This expands services outside of SIUSM to the surrounding community thus beginning to build alliances. May become especially important with growth in the Medical District.

7. Develop the capabilities to conduct all pre-IND development studies as well facilities for Phase I clinical trials. Grow area to be a comprehensive site for taking products from bench to bedside by having the ability to complete development to the point it is more attractive as an out licensing for industry.

Future Development: This item was placed on the faculty survey. This need would require significant administrative and monetary support to hire individuals and build infrastructure initially to support this activity. Could consider a business-oriented person to build and supervise incubators and a biotech corridor.

Prior meeting minutes for the Translational Research subcommittee:

RPC Translational Subcommittee Meeting
January 7, 2008
3:00 PM – 4:00 PM

PRESENT: Teresa Liberati, DVM, Ph.D., Kathleen Campbell, Ph.D., Peter Patrylo, Ph.D.

ABSENT: Louis Premkumar, Ph.D.

Impediments and infrastructure needs for translational research:

For January 14 – Approach

What would be the ideal?

Priority – of all ideas to improve what is primary?

What do we have?

Short falls?

Translational – concept of drug testing, drug development, animal models, what does it encompass?

All bench to bedside no matter which you examine

1) animal model development

2) drug development

3) physiologic parallels between animal models and humans

Carbondale = biotech, some biomedical engineering, devices, - can some services be subcontracted? How does that affect patent? Especially if drug development. Definite need for formulation and drug synthesis.

Divided Areas of Need into Four Areas

Collaborations/Grants:

U mechanism grant = pre IND studies

1. Large # people that work in diverse areas at both campuses so could take drug from industry and look for multiple indications – could do at SIU
2. Collaborative team – multiple disciplines, defend and protect intellectual property. Roadmap – how to put it forward in development. Use project team concept similar to large pharma.
3. Individuals who can compose manuals and data safety management materials. “Manual of Operating Procedures”.
4. Phase III – most clinical trials – at SIU. Not so many Phase II, no Phase I.
5. Could do ROI – mechanism, UOI – development
Match up clinical, have someone do Basic. But not the only model; individuals can do translational as well as ‘teams’.

Educate:

Educate faculty on what and how to do translational – successful models

Educate faculty, students and clinicians on how to do drug development – how to move potential therapies from bench to bedside

Animal model – pathophysiology – translate to human condition

Educate about grants available

Seminars, courses (website)

Individual specialties – how to identify who does what and where?

Do a uniform thing across departments

Biosketch –file these (ADRFA website?)

Retreats that would be useful – cell/molecular and Neurology incorporate translational workshop

Patents, research, grant opportunities include in retreat agendas

Individuals Needed:

Genetics lab – pharmacogenetics = need individual then teach medical students how to use.

Clinicians – need to free up their time to participate; begin to get awards; can help cover salaries.

Licensure

Office – someone who knows biotechs, and pharms, knows their pipelines and development specialities. Someone who can lead due diligence visits

Biotech:

Development of incubator → biotech corridor.

Translational seminar series → informational series

Drug development → outside speakers

Phase I studies – site, need infrastructure

RPC Subcommittee Meeting – Translational Research
January 28, 2008 3pm

Present: Teresa Liberati, Kathy Campbell, Peter Patrylo

Absent: Louis Premkumar, Paula Mackrides

Prioritization of In-House Grant Mechanisms:

Members discussed the grants available through the office of the ADRFA and placed them in the following priority list. Grants supporting faculty who had already demonstrated the ability to receive outside funding but were in a short term need situation were considered of high priority. The Clinician Scientist award was considered lower priority as clinicians could potentially seek funding through K awards that often have less competition. Also, it was asked if monies acquired by clinical departments from the conduct of Phase II-III trials could be earmarked for clinician research projects? The opinion that Concept Development awards are important was expressed, but that the project should clearly have a target of submission for a U award through NIH or be out licensed to industry.

High Priority

- EAM Near-Miss
- CRC Near-Miss
- Bridge
- Concept Development Award

Moderate Priority

- CRC – useful to help acquire preliminary data to support an R grant through NIH

Lower Priority

- EAM – may not go to an R01, consider giving less than \$50,000
- Clinician Scientist Award
- FAAR

Infrastructure Needs at SIU, Carbondale and Springfield

8. Administrative Core – people who have been on review panels for many years and have expertise in grant preparation. Special office that conducts in-house review prior to submission. Also will help with proper paperwork, forms, etc. These are commonly found in other academic settings.
9. Office to liaison with biotech companies and major pharmaceuticals for out licensing, R&D, development, etc. Someone who knows how to tap into these resources and keeps abreast of company profiles, pipelines, market trends, etc. Someone who knows how to handle due-diligence visits.
10. Public Relations – individuals to get the information and research out into the mainstream. Taking little strengths of individual scientists and finding venture capitalists to make investments. Need to be sure correct areas for information sharing are being targeted so can attract the outside investments. Areas of venture capitalists – East and West coast. “Pride solicits Money”.
11. Statisticians – large need for more PhD level individuals with specialties in basic, clinical and translational. Both campuses or could share across campuses.

12. Technology Advancement Office – individuals whose job it is to go out to clinicians and/or faculty and ask what do you need to do your job better? Solicit ideas and match with faculty working in those areas or capable of developing the idea.
13. Increased presence of the Patent Office – offer services to help smaller companies and biotechs develop their idea or file for provisional patents if they are working with SIU. Expand offerings. Add expertise.
14. Develop the capabilities to conduct all pre-IND development studies as well facilities for Phase I clinical trials. Grow area to be a comprehensive site for taking products from bench to bedside by having the ability to complete development to the point it is more attractive as an out licensing for industry.

Potential Survey Questions

For the translational research group survey questions were envisioned to revolve around four main areas: collaboration/grant mechanisms, education, biotechnology corridor development and individuals/infrastructure needs.

Format of interest to the group to use for the survey is to ask a question and have it followed by check boxes. Check boxes could be ranked so that priorities to faculty could be identified instead of just potential interest.

1. How could SIU help you best to apply for translational research opportunities?
 - Aid in the identification of potential collaborators
 - Provide seminars discussing translational research opportunities
 - Hire an individual specializing in the coordination of this type of research
2. Are you aware of the following NIH funding for translational research?
 - U01
3. If the following opportunities to learn about translational research were offered which would you plan on attending?
 - Translational grant workshop
 - Basic Drug Development
 - Patent Filing
 - FDA and IND/NDA filing
 - Technology Transfer
 - Project Teams/Program Projects
4. Do you think having an office for grant application help, i.e. an Administrative Core, that would review all grants, aid in paperwork completion including approvals for human subject inclusion or animal use, would be an asset to your grant submission process?
 - Extremely helpful

- Not helpful
- Would not have time to Use
- Current help is sufficient

5. Identify factors that would enable you to have the time to participate in translational research in a meaningful fashion?

- Better financial incentives
- Less clinical cases/clinic responsibilities
- Less teaching responsibilities
- Greater student involvement in research
- More resources such as an Administrative Office
- Other _____

6. Do you know how and when to apply for a patent?

- Yes, I am very familiar and hold patents
- Yes, I am moderately familiar
- I do not know where the patent office is
- No, not interested

7. Are you familiar with technology transfer?

- Yes, I am very familiar and have participated in
- Yes, I am moderately familiar
- No, unfamiliar
- Not interested

8. Are you aware that for clinical development of a potential product, mechanistic studies are not necessary but could be treated in a separate grant mechanism?

- I am aware of this and would be interested in learning more
- I am aware of this and actively participate in this type of research
- I was not aware of this and would be more interested in participating in translational research
- I was not aware of this, but still would not be interested in translational research or in drug development

9. Do you agree that there is currently a gap at SIU between basic research and Phase III drug trials that needs to be filled?

- No, I am not aware that such a gap exists
- No, I do not feel that such a gap exists
- Yes, but I do not feel it is necessary for SIU to have the capabilities to complete pre-IND, Phase I and Phase II trials
- Yes, I feel that SIU should work toward filling this gap and increasing infrastructure to that end

Steve Verhulst, PhD Humanities and Medical Education Research Report

RPC – Medical Education / Medical Humanities Research – April 2008

The key topics that were discussed to date centered on the notions of establishing and maintaining an externally recognized leadership position for the research agenda of this group or, more generally, the school. It was felt that a generalized term for this combined area of research could be Social and Behavior Research. Several systematic issues that were discussed included: 1) centralization of services, 2) involvement of junior faculty, 3) promotion, and 4) collaboration. In addition, several detailed issues arose that included: 1) a clinical epidemiology core, 2) library shortages and accessibility, 3) long range recruitment plans, and 4) a coordinator of philanthropy specifically for research.

As was noted at the January RPC meeting, several of these topics were also discussed at other subcommittee meetings and the pooling of ideas for the final instruments and discussions should only be beneficial.

In addition these barriers have also been identified:

- 1) Lack of an appropriately aligned set of incentives re education and research for practicing clinicians--e.g., educational / research RVU's
- 2) What is perceived to be a need for more structure for collaboration/communication/integration of interested clinical faculty with DME/Ethics/Social Science Researchers
- 3) A concern that Educational/Ethics/Social Science Research is in a far back seat in the discussions that have been heard so far in the RPC. A concern may remain that the RPC may not be the place to address the research/scholarship agenda and needs of these disciplines.

Sophia Ran, PhD, Basic Science Research was not in attendance at the April 14, 2008 RPC Meeting but her subcommittee's previous report is attached as follows:

I. List of topics: Infrastructure and Services

1. Library issues:

- a. Access to essential articles online
- b. Access to electronic versions of methodology/protocol textbook chapters—The specific methodology books that would be useful are Current Protocols in Protein Science and Current Protocols in Molecular Biology.
- c. Access to Morris Library from Springfield campus and to SIU Springfield Library from Carbondale
- d. Outdated method to track journal use, hard copy and electronic, in both libraries
- e. Lack of electronic titles in particular recently developed research areas (e.g., virology)
- f. Lack of technology to access library resources from outside of SIU campus
- g. Classes on bibliography management, statistical software (in conjunction with biostatisticians), Photoshop and Adobe Illustrator. Another request from Carbondale is File Maker Pro.

2. Large Equipment:

- a. Lack of a dedicated shared equipment room in some departments
- b. Aging or outdated shared equipment in some departments

- c. Lack of institutional or departmental designated funding to maintain large equipment and for service contracts
- d. Lack of proper supervision for maintenance of some shared equipment (e.g., some shared equipment in the Cancer Institute)
- e. Need to upgrade FACS (5 out of 8 responders) – Springfield
- f. Need to upgrade confocal microscope and accompanying software (4 out of 8) – Springfield. Upgrade of confocal is true for Carbondale as well.
- g. Need to purchase and upgrade ultra and high-speed centrifuges, film developer and autoclaves – both departments in Carbondale

3. Core Facilities:

- a. Management of Flow Cytometry facility needs to be improved with regard to competence level of supporting personnel, billing for services and communication with faculty and staff.
- b. Very high vivarium fees in Carbondale will restrict ability to perform animal studies because of the high cost and will negatively affect our research programs
- c. Absence of designated personnel to operate autoclave/ lab washing facility (Springfield) impedes routine lab maintenance
- d. Research Services: lack of communication with faculty who request services; disproportional high fees; lack of appropriate training in many areas
- e. Need to include faculty feed-back on performance, customer relationship and technical competence for support staff of all major core facilities

Note from Carbondale: I would like to acknowledge that the Histology Core in Carbondale is excellent and a huge asset to our research. Costs are low while expertise, reliability and willingness to help are high. Maureen Doran who manages this facility does a great job.

4. Other issues that retard faculty productivity:

- a. Graduate Program at SIU: number of school supported assistantship stipends has not been updated for years and is currently disproportionately low compared with increased number of faculty in the recent years. The low stipend that the Dept. of Physiology Ph.D. students get is a major problem in recruiting quality graduate students. We also think that there should be a more equitable distribution of research assistantships. Currently, the Physiology dept. in Carbondale gets none.
- b. Problems with Human Resources (inefficient communication, lengthy and frustrating hiring process, high rate of fringe benefits; lack of control of salary scale, etc)
- c. Problems with LACUC (delay in protocols' approval because of minute issues irrelevant to animal welfare)
- d. SCHRIS (communication with PIs and lengthy process for protocol approval)
- e. Need to maintain and increase the critical mass of productive research faculty – Number of faculty members is the key for improving research at SIU

II. List of topics: Medical Students and Residents

1. Need to develop innovative approaches to recruit medical students and residents:

- a. Demonstration of institutional interest and support for participating students/residents and those who have interest to participate
- b. Acknowledgment and support of faculty who mentor students/residents in their lab
- c. Need to develop coordinated effort among administration, medical education and research faculty to identify both top interested students and faculty mentors
- d. Need to stress potential of bridging of clinical and basic research by investing in research education for medical students and residents