RESEARCH FACULTY RETREAT - 2006

WORKING GROUP #3

ASSESS KEY (ADMINISTRATIVE) INFRASTRUCTURE COMPONENTS OF THE RESEARCH COMMUNITY AT WFUSM

Leaders: Judy Brunso-Bechtold, Joseph Tobin

Group members: Carlos Ferrario, Jeff Weiner, Steve Peters, John Boehme, Todd Lowther, Mark Miller, Maggie Dailey, Alain Bertoni, Ray Penn, Preston Miller, Beth Hiltbold, Mark Chappell, Bruce King

ExOfficio: Lori Messer, Paula Means, Wesley Byerly, David Friedman

Staff Support: Crystal Reid; Vicky Zickmund

I. INTRODUCTION

The **charge** of the Infrastructure Working Group for the Faculty Retreat on October 20, 2006 was to **assess key infrastructure components of the research community at WFUSM**. This Working Group was co-chaired by Joseph Tobin and Judy Brunso-Bechtold and included Alain Bertoni, John Boehme, Wesley Byerly, Mark Chappell, Maggie Dailey, Carlos Ferrario, David Friedman, Beth Hiltbold, Bruce King, Greg Kucera, Todd Lowther, Paula Means, Lori Messer, Mark Miller, Preston Miller, Raymond Penn, Steve Peters, and Jeff Weiner with support from Crystal Reid and Vicky Zickmund.

Two meetings were held of the full Working Group. During the first meeting, the group met for 2 hours and discussed the elements of infrastructure at the institution that i] had the greatest impact on the research effort of individual investigators and ii] would benefit most from research faculty input. It was decided to break the full group into 5 subcommittees: **Industry Relations/Technology Transfer**, chaired by Mark Miller; **Controller's Office**, chaired by Beth Hiltbold; **Other** (PR/Marketing, Capital Equipment and Space), chaired by Mark Chappell; **Web Resources**, chaired by John Boehme; and **Grant Submission/IRB**, chaired by Raymond Penn. Each subcommittee met several times and, several days prior to the second meeting of the full Working Group, submitted a report that is included here. The reports were reviewed and, during the second 2 hour meeting, the reports were discussed by the Working Group members. That discussion is synthesized at the end of this white paper.

The overarching theme of the discussion among group members was the importance of transparency and communication between the institution and the faculty. For the ultimate success of the research mission, the group felt that the infrastructure must facilitate multidisciplinary and programmatic initiatives and support individual faculty members in those efforts. In addition, each subcommittee concluded that a ***critical flaw in the institutional infrastructure was the inadequacy of the institutional website***. Each subcommittee felt that the infrastructural elements that they evaluated could be strengthened by a more readily navigable, visually appealing, user-friendly website that contained the essential information necessary to successfully and efficiently accomplish the requirements of all phases of research at the institution.

II. INDUSTRY RELATIONS/OTAM

Subcommittee Chair: Mark Miller; Members: Greg Kucera, Carlos Ferrario, David Friedman

A. Charge: This subcommittee evaluated Industry Relations which is charged with negotiating research-related agreements in compliance with legal, regulatory, fiscal and institutional requirements and policies.

B. Agreements:

Industry Relations reviews various agreements with industry (pharmaceutical, medical device, biotechnology, laboratory companies) and other academic institutions including but not limited to:

1. Confidentiality/Non-Disclosure Agreements
2. Material Transfer Agreements (all incoming; outgoing academics only)
3. Clinical Trial Agreements (except for federally or foundation funded)
4. Basic Research Agreements (except for federally or foundation funded)
5. Collaboration Agreements
6. Fellowship Agreements (except for federally or foundation funded)
7. Subcontracts (both incoming/outgoing with industry; incoming with academics except for federally or foundation funded)
8. Services Agreements (Laboratory; Transgenic Mice Development; Other)
9. Unrestricted grants
10. Non-CME conference grants and travel grants (when contracts required)
11. Amendments to any of the above types of agreements

Industry Relations provides guidance and assistance on other agreements as requested. Examples include verification that personal consulting contracts do not conflict with institutional research agreements and questions on key terms, e.g., intellectual property or indemnification, from Grants Administration or Controller's Office on government/foundation funded agreements.

C. Contract Management Activities:

Industry Relations also manages various aspects of research-related agreements including:

1. Checks – receipted/deposited for all contracts we negotiate
2. Budgets – reviewed and approved to ensure correct F&A/fees included; assists with negotiation for agreements and any amendments
3. Close Out – assist with contract close out process including: i) termination notices; ii) overpayment requests; ii) outstanding payments; iv) disputes over funds
4. F&A – addresses questions from faculty, companies, etc., on applicable rate
5. Incoming/Departing Faculty – work with faculty to facilitate transfers in/out of materials, information, contracts, *etc.*

OTHER ACTIVITIES: Industry Relations participates on various task forces that relate to research including: Clinical Trials Billing Task Force, Export Controls Task Force, Vendor Policy Task Force, Vendor/Sponsor Grant/Gift Policy Task Force and Faculty Database Task Force. In addition, Industry Relations presents at various Educational Workshops and Brown Bags.

D. Activity Level:

1. Files Reviewed

   FY03 to FY04 increased 7%
   FY04 to FY05 increased 1%
   FY05 to FY06 increased 14% (includes a 42% increase in Confidentiality Agreements and Subcontracts/Miscellaneous Agreements)

2. Files Completed

   FY05 to FY06 increased 21% (includes 74% increase in Confidentiality Agreements and 33% increase in Material Transfer Agreements)

3. Contracted Dollars (Contracted dollars are represented by all dollars anticipated to be received under all contracts executed through Industry Relations)

   FY04 to FY05 increased 4%
   FY05 to FY06 increased 30%
   Total contracted dollars for FY06 was $23,776,433.

E. Revenue (Per Annual Report):

FY03 to FY04 increased 34%
FY04 to FY05 decreased 22%
FY05 to FY06 (won't be available until early September)

F. Efficiency:

1. Confidentiality Agreements (CAs) – it takes 26 days for CAs to be signed at the Medical Center and 37 days to be fully executed, a 19% decrease in time to completion from last year.

2. Material Transfer Agreements (MTAs) – it takes 38 days to be signed at the Medical Center and 57 days to be fully executed; an increase in time to completion by 2 days.

3. Research Agreements – 100 days to be fully executed, an increase in time to completion of 17 days. Ms. Grace attributed this to the fact that prior to her arrival, IR had not been including language required by the legal department.

G. Strengths:

1. After some issues with employee turnover which is still ongoing, the office has been able to increase the number of agreements being executed with the same staff coupled with a decrease in the time to complete CAs and a relatively stable time to complete MTAs.

2. There has been increased attention paid to budgeting grants and agreements, resulting in more reimbursements to the university; for example, Industry Relations is working to ensure that funds are placed into agreements to reimburse faculty and technician salaries and time on clinical contracts.

3. Increased efforts in conjunction with the legal office to make sure language of contracts does not violate Wake policies.

H. Weaknesses:

Although we did not have time to complete a survey of the faculty, informal discussions with Ms. Grace and with a small group of faculty have raised some areas of concern. These included:

1. The Industry Relations Office has seen a fairly big increase in the amount of agreements it needs to execute and is relatively short staffed. Although efficiency has increased, It has been suggested that two additional positions, in addition to the two already approved, will be necessary to reach the office's goals of reducing the review process on CAs and MTAs to 10 days and Research Agreements to 75 days.

2. There was some concern that communication issues between the faculty and Industry Relations staff exist. In some cases, after several months of effort on an agreement, it appeared that the Industry Office staff was not clear about the scientific issues being addressed. There is also concern that it often takes too long a period of time for Industry Relations staff to process and respond to issues relating to agreements and contracts between institutions. In the case of academic MTAs, there is concern that, since these agreements often have little monetary value, they are given low priority by the Industry Relations office.

I. Recommendations:

1. In regards to staffing, it seems the assessment is that the Industry Relations office will need two additional full-time personnel in addition to the currently approved positions in order to reduce the time to completion of its agreements, which currently take too long.

2. In regards to concerns about communication, the subcommittee felt that it would be helpful to have technical and scientific input early on in the agreement/contract process. This could be easily (and cheaply) accomplished by assigning one or more of the Deputy Associate Deans in the Office of Research to work with Industry Office staff to vet agreements and proposals. In terms of delays in academic MTAs, it should be pointed out that not only are these agreements critical for faculty who need to share reagents with other institutions, but all NIH grantees are required to make their research reagents available to the scientific community. It does not enhance the University's national reputation if we appear unwilling to share the fruits of our research efforts.

Office of Technology Asset Management (OTAM)

A. Charge: The Office of Technology Asset Management (OTAM) manages the intellectual assets of Wake Forest University and the School of Medicine. OTAM works with university faculty, students and staff to commercialize novel discoveries and other intellectual property developed at, or in cooperation with, Wake Forest University and the Wake Forest University School of Medicine. The objective is the development of new products and services that may benefit the public through technology transfer. Commercialization may be through licensing to existing companies or through the creation of new businesses. OTAM works closely with industry, community leaders, scientists, investors, entrepreneurs, and many others to accomplish its commercialization objectives.

B. Management Activities

1. Invention disclosure and patent issues to faculty, student, and staff.

2. Economic development of commercial ideas, the formation of startup companies, and the creation of biotechnology jobs.

3. Revenue generation from the school's intellectual property.

4. License agreements: when it is a WFUHS technology being licensed to a company.

5. Material transfer agreements: when it is a WFUHS material being transferred to a company.

6. Confidentiality agreements: when it is to facilitate out licensing of WFUHS technology.

7. Sponsored research agreements: when they accompany an out-license of a WFUHS technology.

C. Activity Level

1. Patents issued in FY05 totaled 8, down by one (–11%) from FY04. Patent applications filed in FY05 totaled 19, a significant increase over the seven applications filed in FY05.

2. Patent-related expenses are up approximately 34% over the previous year. Patent-related expenses were up significantly at the end of June as a result of annuity payments. Some of these expenses will be reimbursed. In addition, many new patent applications were filed on inventions disclosed from the WFIRM, which currently have no support; these are an investment for future relationships.

3. Invention disclosures are up approximately 33% from the previous year.

4. In addition to licensing revenues, equity was received in FY05, including additional shares of Xenoport common stock, a significant number of warrants to purchase stock of Cortex Pharmaceuticals and Nanomedica, and a large equity position in Isotrace.

5. Miscellaneous Agreements executed in FY05 totaled 50 and included 22 confidentiality agreements with companies, eight materials transfer agreements, one license renegotiation, two memoranda of understanding, nine research agreements reviewed, one consulting agreement, two letters of intent, and five Seed Stage Associates' client agreements.

6. The Office of Technology Asset Management is actively involved in early technology development. Among the promising technologies are:
    - Parallel Firewall for Gigabit Networks – Robert Anderson is formalizing the start-up opportunity. A business plan and executive summary are being created. The working name of the company is Great Wall. We will try to present this company at the upcoming Capital Connection, a venture-capital conference.
    - Carnosine Bars – We continue to evaluate the cost of raw material. Because carnosine is an expensive peptide, the prices of the potential products fall outside the norm.
    - Loggie Catheter – The Inception Micro Angel Fund and SpringMed (serial entrepreneur Jon Wilson's local medical device incubator) have expressed strong interest in this technology for further development.

7. Historically, 1/2 to 2/3 of the patents processed by OTAM get licensed to a company.

OTHER ACTIVITIES

Seed Stage Associates (SSA). SSA was awarded a contract renewal to provide a third year of technology transfer services to the UNC System. The contract was expanded to include UNC Wilmington, UNC Pembroke, Fayetteville State University, and Elizabeth City State University, for a total of 11 universities served. Our fees increased by 50%, and this increase will allow SSA to hire a 0.5 FTE to cover the clients in the eastern part of North Carolina. This expansion

allows SSA to access the technology development activities of most of the UNC system and to solidify our national reputation as a center of technology transfer expertise.

Child'sMind Publishing has continued to service its client institutions. The Forsyth County school system is currently evaluating a significant pilot project to provide the predictive assessment of reading, PAR to K-3 in 11 schools. We are working with Wake County and Forsyth County school systems to craft a grant proposal to the Z. Smith Reynolds Foundation to apply PAR system-wide in those counties. Sarasota County, Florida, is currently evaluating a system-wide implementation of PAR.

D. Revenue (Fiscal Year 2005)

1. Licensing revenue increased approximately 44% during the previous year-to-date to a new record of $49,415,067.

2. This year OTAM has paid $24.5 million to 16 different inventors and $4.87 million to seven different departments.

3. Ten license or option agreements were signed last quarter with several different companies, an increase of 42.8%.

4. OTAM activities are expected to bring in a total of ~$70 million in FY07.

Comparison of Activity for Fiscal Years 2001 through 2005

Activity	FY01	FY02	FY03	FY04	FY05
Inventions Disclosed	37	36	38	30	40
U.S. Patents Issued	15	9	9	9	8
New U.S. Patent Applications Filed	14	11	7	7	19
Option/License Agreements	12	11	12	7	10
Start-up Companies Created	1	0	1	1	*
Licensing Revenues	$9,388,500	$17,886,000	$19,318,000	$34,296,000	$49,415,067

E. Recommendations

Dean Stell outlined the 3 potential models that OTAM could use to define its mission – a revenue model, faculty service model, or an economic development model. OTAM has used the revenue model. In this case, OTAM staff picks potential "winners" and discard potential "losers" in assessing what patents, inventions, and ideas should receive attention and funding from the university. This raises three issues:

1) By definition, OTAM will necessarily have some faculty who are unhappy about being triaged out of the process.
2) There is the possibility that some really good ideas could be discarded or really bad ones promoted.
3) Who gets to make these decisions?

The committee felt that more faculty input into issue 3 – the decision making process – would enhance the interaction between faculty and OTAM and provide for a more transparent process. This could be through a Dean's advisory committee or via a mechanism involving Assistant Dean's from the Office of Research as early liaisons in the process.

Minor note – For both the Industry Office and OTAM, it would improve their profile in the university if office staff made an effort to contact every department in the university (both campuses) and offer to give a 10 to 15 minute talk on what they do, how to contact them, and what the process is entails. This would raise their visibility and provide faculty with the information they need to contact the right people early in the process of preparing agreements, contracts, licenses, or patents.

III. CONTROLLER'S OFFICE
Subcommittee Chair: Beth Hiltbold; Members: Paula Means, Maggie Dailey, Joseph Tobin

Charge: This subcommittee determined common issues which impede the success of investigators doing research with regard to financial dealings with the Controller's Office. Further, to understand the scope of responsibilities of the office and to identify potential solutions to the issues raised given that knowledge.

Approach: Selected faculty from each department were polled by survey questionnaire. Two faculty from each department were polled, one senior and one junior, who had grant awards/accounts and financial administrators from each department were welcomed to respond as well. Working with the Controller's Office, the questionnaire was developed to query potential issues perceived by the faculty as well as those pointed out by the controller's office personnel. A set of 9 questions were posed concerning pre-award issues, post-award issues and more general suggestions and comments. The compiled results of these responses are listed below.

Data: The surveys revealed the following

- **Budget review:** Generally satisfactory with the only complaints being timeliness of review

- **Controller's Office/budget preparation tools:** The overwhelming response was that the website was either not used or the faculty were not aware that there was a website

- **Closing out grant accounts:** While many found this process to be adequate, there were several complaints including the amount of time it takes to close out the account after the grant ends and errors in expenditures which result in large overages. These issues made it difficult to manage the accounts.

- **Establishment and management of accounts on grant awards:** This was largely positive, with only a few issues which included the timeliness of account setup and the allocation of monies in spending categories which often required significant re-budgeting.

  One complaint was that Request for Payment forms typically come back with questions. It was suggested that this would be better dealt with by phone instead of being returned with a cover sheet which often does not clearly describe the problem.

- **Communication between departments and faculty with the controller's office:** Most faculty responded that they prefer to communicate with the CO through their departmental financial administrator, however, some complained that if faculty tried to reach the controller's office personnel, their calls and emails were not returned. **A fundamental issue was identified** that many departments have administrators devoted specifically to grants/accounts/finances while others do not. This was seen as a significant disadvantage to faculty in departments without such administrators.

- **Suggestions on monthly grant expenditure summaries:** One suggestion was to include the salary/fringe detail with the non-personnel detail so as not to require two reports each month. Other suggestions included providing the reports in a more timely manner, make encumbrances more clear, provide better detail on when and how deposits are made and when indirects are taken out, make statements more understandable to non-accountants, and highlight summary of what is left in each account by major categories

- **Suggestions for monthly effort certifications:** This system was generally regarded as fine with only a few suggestions for improvement. These included making these more available to administrators so they can assist faculty and staff with the completion of these forms, making it clearer to clinical faculty the difference between these and Green sheets, and clearer effort reporting categories and the inclusion of a line item for indirects on the statement.

- **Financial Research Compliance Workshops:** There was lots of positive feedback on these. Suggestions included offering shorter workshops and make them available online.

- **Comments, suggestions, or positive feedback:** Specific positive comments were made about several of the Controllers office personnel and of the general friendliness and ease of working with the office. Suggestions included shortening the chartfield numbers, responses to phone and emails should be more expeditious, that the staff be more highly qualified or trained with grants and be better paid, better communication between the office of research and the controllers office, moving some of the management of grants back to the departments,

Strengths- most felt that the controller's office was friendly and efficient in support of the research mission. Several of the personnel were specifically commended for excellence.

Weaknesses- the majority of complaints were centered around the closeout of accounts, with regard to timeliness and errors in reporting final balances. Other weaknesses included lack of use or knowledge of the website, establishment of accounts with regard to distribution of monies and requests for payment, and the timeliness of monthly summary sheets.

Barriers to Success: There were many suggestions that the Controller's office employ a more highly trained workforce and pay them better. Furthermore, departments that do not have dedicated financial administrators put their faculty at a significant disadvantage in the preparation of grant applications.

Summary/Conclusions- There was an overall positive response to the job that the controller's office is doing. However, there were a few suggestions and recommendations as listed below.

Recommendations:
General- The accuracy and timeliness of account closure and monthly statements should be improved. Statements are generally available on the 10th day of the next month after the monthly close process. It is possible that some delays may occur at the department level (via distribution of statements). Information is available through the standard monthly reports, as well as real-time/on line access through PeopleSoft.

Close out of accounts is a priority for the Controller's Office as well. Given the steps involved it is imperative that the Controller's Office and a given department work closely together. For example, if people are not removed from a project, the account cannot be closed, and this action can only be initiated at the departmental level. The new cost transfer forms which were implemented this past spring are one of the first steps being taken to adhere to federal regulations and address the issues of timely closeout of grants.

Specific- Website should be more visible, accessible, and user friendly. The Controller's Office website is designed for only internal users and thus cannot be accessed outside of WFUBMC's intranet. The website is very simple and contains information such as a fringe calculator, expense code definitions, travel policies, and many useful links. Many questions that investigators have are often posted under the FAQ link found on the right hand side of the Controller's Office screens.

Issues identified but not addressed or unable to come to consensus:
Some faculty felt that the Controller's Office had too strong a regulating role in dispensing funds based on approval from other committees such as IRB. The Controller's Office is bound to enforce federal regulations; however, if there are exceptions that need to be explained, these are often addressed between the IRB, the PI and the Controller's Office.

Another suggestion was to include personnel salary and fringe detail on the monthly statements. Personnel information such as salary and fringe are part of the PS HR module. Although links are established between the two systems, it takes considerable programming time to do so. Other concerns with HR data (salaries) center around confidentiality and security issues.

Overall it is important to recognize that information and processes are often governed by many different kinds of regulations (NIH guidelines, federal regulations, GAAP standards, IRS tax laws, etc.) and even when it appears not to make sense to all users, the Controller's Office strives to make financial reporting as simple as possible and welcomes all suggestions/feedback.

Background: Responsibilities of the Controller's Office

The Controller's Office is a centralized administrative office, whose mission is to provide timely and accurate financial and accounting services while maintaining a helpful, customer service focused environment. The Special and Sponsored Funds section of the Controller's Office is the primary contact for research financial related questions. Within the Special and Sponsored funds section the following activities are managed:

- Review budgets being submitted as proposals
- Account set up
- Management of the expenditures which includes:
  Approval of Requisitions and Request for Payment (RFP)
  Approval of all HR actions related to sponsored accounts
  Manage/approve monthly internal transfers

Writing subcontract agreements for funds being issued to other institutions under extramural funds
Managing the subcontract financials
Management of transfers via JE (Journal Entry) including cost transfers

- Monthly invoicing to sponsors and/or reporting of financial activities
- Close out of accounts including Financial Status Reports (FSR)
- Answering questions/assisting faculty & staff regarding rules and regulations of expenditures
- Management of Effort reporting
- Termination notices, relinquishing forms
- Billing and collecting from various sponsors including Letter of Credit draws.
- Various other compliance reports (such as Small business reports and Governmental property reports)
- Various financial analysis

Each Grant accountant typically manages 300- 600 grant accounts and works with various staff and faculty in several different departments to effectively manage the grant financial activities. In addition to the above, the following tasks involve other Controller's Office section as well the Sponsored and Special Funds section:

- Assist with facilities and administrative proposals; what if analysis, as well as the final negotiation with the federal government
- Prepare/assist auditors with annual financial statements (A-133 and other sponsor mandated audits)
- Prepare/analyze fringe benefit rate calculations and related cost analyses and studies as appropriate.
- Ensure property purchased from sponsored funds is authorized, properly recorded, tagged and ultimately disposed of
- Assure WFUHS fully complies with sub recipient monitoring regulations
- Review and approve service center rates, providing strategic direction and related reports and recommendations.
- Various training related activities (technical/system modifications and recommendations as needed.)
- Advise management of changes in regulations and issues related to maintaining institutional policies.

The Controller's Office and the Office of Research also should work closely together in an effort to make the life cycle of a grant as seamless as possible. Both offices manage various aspects of the grant management process throughout the grant's lifecycle and they should communicate often to ensure that processes flow as well as possible.

IV. OTHER (PR/MARKETING, CAPITAL EQUIPMENT and SPACE)
Subcommittee Chair: Mark Chappell; Members: David Friedman, Jeff Weiner

A. Charge: This subcommittee assessed the current approach to the allocation and review of laboratory space within the School of Medicine at Wake Forest University. Space is an important and very limited resource at the Medical Center; the proper allocation of space is key to rewarding successful investigators and/or programs and providing for expansion of existing and new programs in the future.

Approach: The committee members interviewed Tim Bell, Director of Physical Resources and Laurie Molloy, Assistant Dean for Resource Management.

Main Finding/Recommendations:

1. As discussed, the issue of space within departments and centers, or for individual investigators is difficult due to the influence of many factors that now include compliance particularly in the older research labs such as those located in the Gray building. In lieu of the compliance issue and the associated costs, assignment of available laboratory space must be considered in accordance with the current fire and safety regulations.
    - Purpose of building (i.e. CSB – patient clinics and trials; NRC, Gray Hanes – no patients)
    - Balance chemical load in labs
    - Fire safety requirements
    - Appropriate fit of space for need – limit renovations and change of purpose
    - Adjacencies for department, program, or collaboration needs
    - Productivity – number of bodies in lab, grant dollars (direct/indirect), equipment space requirements, etc.

2. Information regarding new or vacant laboratory space should be available on the Web that may facilitate either the planning for permanent space or for temporary location. This temporary or swing space may be utilized to address an acute need of overcrowding, creation of a core facility or to facilitate collaboration among investigators on mutual research projects for future funding.

3. Information regarding the overall plan to meet the current and future needs for research space should be available on the website, as well as the current guidelines for allocation and review of laboratory space.

4. Although allocation of space solely for directed research is not recommended, the consideration of laboratory space to promote multi-departmental and multi-disciplinary collaboration is advised, particularly given the current funding environment and the fragmentation of research departments away from the medical school campus.

5. Although not discussed, the allocation and need for animal housing in association with laboratory space for investigators among the different campuses should be addressed.

6. Given the acute need for laboratory space and the limited resources, it is not clear that a rational system exists to facilitate the allocation of space to the more deserving investigators. It is recommended that an audit of investigators be considered that encompasses a point system based on their current research, teaching and service areas in lieu of awarding laboratory space. A number of measures should be incorporated including publication productivity and importance, direct and indirect costs of the sponsored research, and the number of research trainees.

7. To better achieve these aims, it is recommended that a research faculty committee for space allocation and utilization be initiated. This committee would serve in an advisory capacity to the Dean to offer recommendations on research space. Similar to the IRSC for intramural support, the committee would review applications and proposals for laboratory space and forward their recommendations to the Dean.

B. Public Relations

Approach: The committee interviewed Jan Strohl (Senior Marketing Manager, E-Business, Office of Public Relations and Marketing) and Karen Richardson (Senior Media Relations Manager, Office of Public Relations and Marketing) to assess current Web and public relations-related resources, as well as Doug Byrd (Systems Administrator, Physiology and Pharmacology) and discussed faculty-related issues within subgroup.

Main Findings:

- Jan Strohl, along with two support staff, is responsible for the maintenance and overall content of the institutional website. The organizational structure of the WFUBMC website is largely divided under "clinical" and "medical school" headings.

- Over the last few years, "traffic" on the institutional website has risen steadily. However, there is a general concern that this potentially valuable resource is being underutilized at both the departmental and individual faculty member level.

- Currently, each Department/Research Center appoints a single individual who is responsible for the maintenance of each local website. Since these individuals have varying levels of Web experience and time resources available, the content and appearance of local websites is variable. Ultimately, departmental chairs are responsible for the local content of their respective departmental Web pages.

- The institution switched to a "content management system" several years ago, in part to ensure that all Web pages exhibit appropriate branding (recognizable as WFU websites). While this change facilitates the regulation of the website at the institutional level, departmental Web managers and individual faculty expressed concerns about template restrictions, ease of use, and the general efficiency of maintaining/updating Web pages under the current system.

- The E-business department currently offers quarterly training sessions for local Web managers on Web-related issues and individual instruction/support upon request. There is a general consensus among local Web managers and faculty that additional Web training and support resources are needed to ensure that this potentially valuable resource is being used to its full potential.

- Faculty identified several areas where the institutional website could be improved/better utilized:

    a) Departmental/Faculty Web pages are a potentially valuable marketing tool in the recruitment of new students, post doctoral fellows, and faculty recruits. Additional resources/training could help local Web managers and faculty members improve the content and appearance of their Web pages to take maximal advantage of this resource.

    b) With the growth of the "Downtown Campus", the institutional website may represent an effective portal to facilitate communication within and between departments (e.g. virtual bulletin board for departmental seminars).

c) Departmental/Faculty Web pages could also used to improve communication between the departments and the lay community (e.g. facilitate outreach programs, interactions with local schools and organizations, etc…).

d) By improving keyword-based search functions, faculty Web pages could also be used to identify individual faculty members by research expertise rather than solely by departmental affiliation.

- With respect to Marketing-related issues, most faculty members felt that there are currently adequate resources available through the Office of Research to meet their "Public Relations" needs. There was some concern that faculty members may not be adequately using these services to communicate their research findings to the media and the lay community at large. Better communication between the Public Relations department and research departments about services and resources available may help to resolve this problem.

V. WEB RESOURCES
Subcommittee Chair: John Boehme; Members: Todd Lowther, Alain Bertoni, and Bruce King

Charge: This subcommittee A) determined Web-related resources that would support research productivity, B) assessed relations-related resources/services available to research faculty, and C) sought to determine if these resources are adequate to meet the faculty's needs.

Discussion: The committee identified various information categories that, if streamlined and organized, could potentially increase communication to the research community regarding research protocols on both campuses. Discussion topics are as follows:

1) WFUHS flow chart on how to start a grant
2) WFUHS/WFU flow chart on how to start a grant
3) How to create a clinical trial
4) How to find an industry contact
5) How to perform technology transfer
6) Review of internal communications for research- internal/external website
7) Communication with the Controller's Office
8) NIH electronic submission

The committee identified that some of the above listed topics were found on the following websites, they are as follows:

1) Office of Research website
2) WFUBMC external website
3) WFUBMC internal website (Intranet or Infinet)
4) WFU website
5) WFUBSM Controller's Office website

Recommendations:
1) There appears to be a fair amount of research information available in both electronic and paper formats located on various websites throughout multiple departments and offices. It would be useful to perform an inventory of all departments that support research activities and localize all research-related information so it is clearly visible and readily accessible. A gap analysis could be

performed on the inventory to identify useful research content that is not represented.

2) Once the gap analysis is performed the following actions are recommended: a) review and update existing research content and b) develop new content

3) As described in item 1, the existing research content is scattered throughout various departments. It is recommended that a central electronic repository (Web links) be established that manages all of the key research content (process and informative content). Proposed locations would be the websites of the Office of Research (WFUHS) and of the Office of Research and Sponsored Programs (WFU).

4) Based upon responses from the Web Resource survey the faculty database project should continue. It is recommended that the database provide key research and contact data only, therefore minimizing on-going faculty maintenance for updates. An efficient database could be very helpful for communication between the two campuses.

5) Considering implementing Web forums for research discussion.

VI. GRANT SUBMISSION/IRB
Subcommittee Chair: Raymond Penn; Members: Stephen Peters, Lori Messer, and Wesley Byerly

Findings: The committee identified what was felt to be both strengths and weaknesses in the grants submission process. Discussion focused on:

a) the mechanics of IRB submissions;

b) the role of a Web-based flow chart "Tool-kit" enabling more expedient and efficient submission and processing of all grant components;

c) the importance of administrative support, based in departments and centers, capable of efficient interaction with Office of Research, controller's office, other departments/centers/ schools, etc.;

d) the need for a decision making and educational process that identifies in advance priorities in extramural funding, institutional strengths (investigators and physical resources) that exist or are required in to compete for such funding; and

e) Institutional financial support to help generate competitive applications, particularly for programmatic funding.

Recommendations:

1. eIRB represents a significant improvement in the processing and approval of IRB proposals. One area that might be improved relates to the ability to evaluate simultaneously pending amendments to a given IRB proposal. Currently, only one pending amendment can be considered at a time. A similar electronic submission process should be developed for the ACUC.

2. Pre-review of processes important to grant submission (e.g., initial Grant, IRB and ACUC proposals) appears to be helpful in expediting successful applications; all pre-review processes should be maintained and perhaps expanded.

3. OR should consider creating a proposal "tool kit" for their Web page. This tool kit could incorporate existing resources with new resources in an easy to use format. This is a link to the UNC proposal tool kit:
http://research.unc.edu/osr/proposal/index.php

4. PI's/Department Support Staff should involve the Reynolda Campus Office of Research and Sponsored Programs early in the proposal development process. Although the process has improved over the past few years, there are still times when the Reynolda Campus is not asked for a budget until the day the proposal needs to be sent to the Controller's Office/OR for review. A continued focus on training of departmental proposal development staff is needed to ensure consistency across all departments.

5. A mechanism for providing substantive, consultative scientific review of applications during proposal development should be developed. This process would provide a peer review forum to help investigators strengthen the scientific and methodological quality of proposals prior to submission. This review process is distinct from the administrative and regulatory review already in place. While the work of the "mini study sections" and the research core is acknowledged, this type of support and review should be expanded and strengthened.

6. A process to identify topics and areas that are likely to be the focus of future funding opportunities should be established. This would allow investigators and the institution to begin to develop pilot data and assemble the resources needed to respond to upcoming initiatives.

7. Although there is a consensus that WFUHS has several key strengths that could cooperate and lead to programmatic funding, mechanisms that bring investigators together who are capable of scientific "synergy" leading to extramural funding, are still lacking. Both formal and informal forums should be developed and facilitated to help stimulate multidisciplinary research

8. Communication of the Institution's strategic research planning to all members of the faculty needs to be strengthened. A clear understanding of how the Institution envisions current and future research strengths will assist individual faculty members to *organize and prepare* to compete for specific funding opportunities in the future.

9. A need exists for institutional financial support of planning and data generation for *programmatic funding*. In today's funding environment, most investigators, or investigative teams, do not have sufficient discretionary funds to support work necessary for the generation of PPGs or other types of programmatic funding. As a consequence, few attempts are made to even discuss multi-grant applications. What might be helpful is a mechanism that reviews and funds proposals seeking to develop applications for specific programmatic funding.

VII. SYNTHESIS

The infrastructure evaluation subcommittee examined many but not all domains of infrastructure support for research. This discussion highlights the recent progress in some domains and challenges ahead.

Significant progress has been identified by the committee in multiple domains. In particular, there was an expression of satisfaction with interpersonal interaction of investigators with many members of the infrastructure staff throughout the institution. Notably, the most common themes that emerged for consideration were advancing the number and educational level of staff, and applying resources to Web-based initiatives to simplify grants submission, grants tracking and education of the entire research community of opportunities not yet leveraged.

Web-Based Resource Developments

Electronic information and logistics support were the most notable priorities to enhance recruitment and retention of researchers, recruit students, develop more interdepartmental collaborations, simplify the grants application process and processing. Whether the term 'tool kit' applies, the following resources are suggested for development:

1. Updated websites for faculty, departments, research publications, recent awards to investigators and departments (honorary or financial). This would improve our recruitment of students and possibly other faculty and staff.

2. Develop a robust internal search engine which permits all WFUSM/WFU faculty access to current research fields of interest of other faculty. These may be interests that share similar techniques or technology, or shared scientific fields of pursuit. This may facilitate the development of multi-departmental and cross-campus initiatives.

3. Develop a primer for new investigators, graduate students and postdoctoral fellows. This primer would be an 'how to guide' to navigate the systems enabling faculty to:

   - identify grant sources (NIH, non-NIH foundations, DoD, DoE, FDA, specialty based starter grants),

   - provide a grants submission algorithm for the first time applicant. This would educate the investigator to key contacts in the institution, regulatory requirements involving their research (e.g. Biohazards, radiation, animal care, GCRC and IRB), Controller's Office and Office of Industry Relations/Technology Transfer. At a minimum, this primer could elucidate the initial steps of grantsmanship, and provide key contacts for investigators as they deal with changing regulatory requirements and unique aspects associated with so many different granting mechanisms. Key contact persons in each infrastructure section should be clearly identified as point persons of first contact.

4. Develop a weekly/monthly schedule of research related events for all researchers to have access to. This would include all research seminars, visiting professors, grand rounds presentations, WFU Reynolda campus scientific presentations, etc.

Web based resources will need to be addressed and appropriate personnel and a reporting system should be developed. Web infrastructure and resources must be expanded considering

the increased internet traffic anticipated. Updating the Web with weekly and timely events is time consuming, but does not require significant bricks and mortar resources.

Significant variability exists in the knowledge/skill levels and percent effort distribution of departmental LAN administrators. A content management system has been required across the entire institution. Many departmental LAN administrators will need further educational contact time to deal with Web-based initiatives (currently only 4 meetings/year), and sufficient time for departmental website updating, and/or providing information in a timely fashion to the webmaster for posting. We are of the opinion that we need to leverage the Web to recruit students, facilitate communication across the campuses (e.g. schedule of all seminars – 'What's happening this week?'), and improve the information and logistics for investigators throughout the institution.

Web communications: tools or information to get research accomplished – We should develop a 'grants flow diagram' for new investigators. Similarly, a program/algorithm diagram for 'how to get going in a clinical trial?' should be developed and posted. NIH electronic submission webinar/podcast to educate investigators would be useful. Our committee did not come to a conclusion as to where to centralize these pages. Faculty did express concern that updated posted material on departmental or investigator's websites should not contain confidential material or other intellectual property that might be disadvantageous for investigators.

Another suggestion included access to models of successful grants – equipment or construction, small grant mechanisms, supplemental award, minority supplement, DOD, etc. The committee also concluded that a robust search engine – with utilities or resources (e.g. fringe benefit calculator, CRISP database, foundation grants listing, RFPs), would be useful.

The Subcommittee Survey instrument is attached as Appendix A.

Controller's Office

The strengths and weaknesses identified in the Controller's Office report are detailed earlier in this document. The Subcommittee Survey instrument is attached as Appendix B. Faculty responses included the satisfaction with the interpersonal communications with the Contoller's Office, but identified opportunities for improvement. Suggestions were made to enhance the educational levels of Controller's Office personnel and have Human Resources reevaluate job descriptions to develop higher pay grades appropriate with their many job functions. With the complexity of regulations, investigators and their staff members (laboratory technicians) may be significantly assisted if departments each had a financial administrator. This would reduce PI frustration, loss of technician time, and an educated/experienced departmental official could more competently challenge the regulatory interpretation of the Controller's Office.

Specific pre-award, award and post-award recommendations are noted. Expediency in closing out grant accounts may reduce significant errors in expenditures, and improve management of accounts. Line item reporting could be enhanced for better understanding by non-financial managers.

Industry Relations

Similar comments were expressed about insufficient staffing of the Industry Relations Office. As WFUSM wishes to diversify its sources of revenue, Industry Relations is an important infrastructure to be enhanced. As industry grants grow, the return on investment will be significant. Further, industry is requiring faster responses from academic investigators and their regulatory offices to participate in industry related research. Many faculty have insufficient entrepreneurial acumen to understand the complexities involved with industry-sponsored

research. We should develop a Web-based education module for Industry Relations, and a step by step guide (getting started) for investigators. Scholarship, conflict of interest, financing and other topics could be developed as other secondary modules. A representative from Industry Relations could make short presentations at either individual departmental faculty meetings or the annual faculty meetings to enhance visibility of the office.

Office of Technology Asset Management (OTAM)
The OTAM has had significant growth and success over the past 5 years. With the intention of diversifying income sources, the OTAM is in a pivotal position to enhance revenues along with providing service to faculty members. With limited resources, it is of concern that possible important developments may not be highlighted and some faculty members will not benefit from OTAM due to resource limitations. This should be monitored and appropriate resources enhanced as opportunities arise.

Grants Submission Process – Office of Research
Significant improvements have occurred with the development of eIRB for grants submission. Although the logistics of the grants submission process have been well addressed, the early scientific review and interactions with investigators needs continued advancement and resources. Aligning investigators' interests with high priority opportunities for funding should be identified.

Faculty expressed concern regarding the climate of cooperation in the perception of success by RO1 applications as PI above any cooperative approach to multi-departmental or multi-institutional grants participation. These concerns included departmental chair's satisfaction and RRPT evaluation of success as a PPG project director vs. PI on a RO1. This is being addressed by both the NIH and our institution. WFUSM needs to focus on programmatic themes for research, and support the cooperation of faculty in these applications. Our committee suggested the formation of a strategic planning committee to identify our strengths or areas of experience.

APPENDIX A Web Subcommittee Questionnaire

OBJECTIVE: Determine Web Resources that will enable Research Productivity

DISCUSSION: The committee met and discussed basic communication forums that were needed to support the research community. Some of the topics discussed are as follows:

1. WFUHS flow chart on how to start a grant
2. WFUHS/WFU flow chart on how to start a grant
3. How to create a clinical trial
4. How to find an industry contact
5. How to perform tech transfer
6. Are internal communications via the web site (internal or external) adequate for researchers
7. Communication with Controller's Office
8. NIH electronic submission

Web resources that provide some support of the above stated requirements are as follows:

1. Office of Research web site
2. WFUBMC external web site
3. WFUBNC internal web site (Intranet or Infinet)
4. WFU web site
5. WFUBMC Controller's web site

Based on the objective of determining key web resources that would support the research community with access to streamlined research process information the following questions are provided for comment.

1. Would a systemic basic review of all research processes content such as in areas stated above be important to document in terms of value, thoroughness, and location?

   For Example: For WFU and WFUHS or combined campus grants.
   a) How to start a grant.
   b) Procedures to follow once grant/contract is secured.

2. If so, would it be helpful to electronically link all the key information?

3. If key research process was reviewed and simplified where would be the most optimal web site to place this information?

4. Would a faculty database that obtains information such as research interests, current and past grants, and citations be valuable? (This project is currently under review)

5. For those of you that know about the eWake education portal would it be supportive to have a similar portal that allowed each researcher to tailor their own area with pertinent electronic information that would benefit the individual researcher? Information that could be included in a personal portal would be web links to your favorite public/private funding agencies, electronic copies of all your grant applications, manuscripts, etc

6. Other suggestions not listed that you feel would be important to consider regarding web resources that would promote research productivity?

APPENDIX B

Controller's Office Subcommittee Survey

Objective: To obtain feedback on current or recent experiences of faculty and/or departmental grants administrators with the Controllers Office in order to identify issues and initiate the development of ideas for potential solutions. As a first step toward enhancing the ease and efficiency of interactions between faculty and the controller's office with regard to grant applications and awards, we request your responses to the following questions:

Pre-award/application issues

1. Under the current system, budgets on grant applications must be reviewed by the controller's office. Would you rate your most recent experience with this review process as satisfactory?

If no, please briefly comment

2. Was the controller's office website of use as you prepared your budgets (such as tools for calculating fringe cost)?

If not, please comment briefly

Post-award issues

3. Have you recently closed out a grant award (from NIH, industry, WFU venture funds or other funding agency), and if so, was your experience with the controller's office satisfactory in this process?

If not, please briefly comment.
4. Were you satisfied with your most recent experience with the establishment and management of accounts on grant awards?

If not, please elaborate

5. Do you prefer to speak directly with the controller's office staff when you have questions or issues regarding your budgets or accounts or do you prefer to have your departmental financial administrator handle those questions?

6. Do you have any suggestions on how monthly grant expenditure summaries may be improved?

General

7. Do you have any general comments, suggestions, or positive feedback for the controller's office?

8. The current monthly effort certification system utilizes online reporting and a 30 day due date. Would you prefer to certify more often (quarterly)? Would you like to see more instruction

offered on efforts? If so, please specify areas/topics of guidance desired. Do you have any suggestions to improve our current system?

9. Staff have recently been required by Compliance to complete a Financial Research Compliance Workshops before the Controller's Office can establish the staff member as an approver in PeopleSoft. This workshop provides grant related information, including institutional processes and procedures information. Do you have any suggestions or comments on this new procedure? Would you be interested in a similar support opportunity?