

Stony Brook School of Medicine  
Faculty Senate Meeting  
January 23<sup>rd</sup>, 2007

Dr. Cedric Priebe (Presiding)  
Dr. Scott Johnson (Recording)  
Attendance: Please see attendance roster.

Dr. Priebe called the meeting to order at 5:05 pm.

**I. Review of Minutes of Meeting of November 28<sup>th</sup>, 2006: Dr. Johnson**

- Minutes of the November 28<sup>th</sup> 2006 meeting were accepted as written, without changes. Dr. Priebe asked that if anyone had any questions or concerns regarding the previous minutes to address them with him or S.Johnson.

**II. Report from the Dean of the SOM Dr. Fine**

- Dr. Fine commented that the Dean's office is very supportive of initiatives to stimulate more research, and to enhance the quality and magnitude of research at this institution.
- Dr. Fine reiterated the importance of the CTSA. Translational research is a very important topic for the NIH and that we must achieve success with the CTSA endeavor for the SOM to succeed and prosper.
- Dr. Fine thanked Dr. Priebe for organizing this very important research forum.

**III. Expert panel presentation: "Help to do Clinical Research" Expert Panel**

- Dr. Gail Habicht, VP for Research
  - Dr. Habicht introduced the research faculty panel and gave a brief introduction to the program.
  - She stated that there are a number of resources for clinical research here on campus; some on the West campus and some here on the East campus.
  - She stated that her main message was that if any faculty member has any questions regarding research in the clinical research arena, all they need to do is ask!
  - She suggested you share your ambitions with your colleagues, so that they can advise you on proposal preparations. You must also share your ideas with your department chair so he/she can commit space and time to your research endeavors.
- Dr. Leslie Hyman, Preventive Medicine
  - Dr. Hyman addressed how one begins on a research path.
  - Where do questions come from?
    - Need to know a lot about the problem
    - Need to understand the boundary between current knowledge and ignorance
    - Must be able to research the question
    - Astute observation
    - Notice new, changing patterns among your patients
    - Careful, critical reading of medical literature
      - *Use the literature to identify unresolved questions*
    - Pursue treatment/patient management issues that don't have clear cut answers
  - Finer Criteria for a good research question

- Feasible (*adequate subjects ,expertise, affordable, manageable in scope*)
- Interesting (*to investigator and others*)
- Novel (*Confirms/refutes prior findings, extends previous findings, new findings*)
- Ethical
- Relevant (*scientific knowledge ,clinical/health policy, future research*)
  - Ref- Hulley, Cummings et al
- HOW TO GET STARTED-*Training opportunities in the SOM*
  - Clinical research course
    - Overview of major topics
    - Jan. 9-Feb. 9; 3-5:30 pm Monday-Friday
    - Organized through Master in Public Health (MPH) Program (Drs. Ray Goldsteen/Mohammed Saad)
  - Clinical Research Training Program (K30 award)
    - 2 year training program to provide in-depth training
    - Includes 1 year curriculum; Certificate in Clinical Research
    - Credits applicable towards MPH/Evaluative Sciences
    - Application deadline Feb. 1, 2007
    - <http://www.osa.sunysb.edu/k30/>
  - Graduate Program in Public Health
    - Director, Ray Goldsteen PhD, Professor, Department of Preventive Medicine
    - [http://www.stonybrookmedicalcenter.org/education/public\\_health](http://www.stonybrookmedicalcenter.org/education/public_health)
  - SOM Clinical Research Resources/Opportunities
    - Biostatistical Consulting Core:
      - Director, John Chen PhD, Associate Professor, Department of Preventive Medicine
      - <http://www.uhmc.sunysb.edu/prevmed/biostat.htm>
    - General Clinical Research Center (GCRC):
      - Director, Marie Gelato MD, PhD, Professor, Department of Medicine
      - <http://indigo.gcrc.sunysb.edu/>
    - Women in Medicine: Research Day
      - Wed. April 18, 2007
- Dr Marie Gelato, GCRC Director
  - Funded by an NIH award of over \$1 million per year for operation
  - The mandate for the GCRC is to provide resources for all investigator initiated studies that use human subjects.
  - Provides infrastructure for investigator initiated research on human subjects.
  - Funding for project is not required to utilize the GCRC
  - Serves as both an inpatient and outpatient unit- located on the 12<sup>th</sup> floor, south corridor of UH.
  - “GCRC without walls” where nurses travel to other areas to assist investigators
  - Phone contacts:
  - GCRC Unit on 12 south- 41200
  - Administrative Director, Nancy Wyllie - 4 6900
  - Nurse Manager, Tracy Dourdonas- 4 7662
  - Systems Manager&Informatics, David Cyrille- 47399
  - Biostatistics, Dr.Ahn - 46900
  - Biostat&Data Management, Shilpi Kahn- 46950

- Core Lab, Dr.McNurlan- 48095
- Our website: <http://indigo.gcrc.sunysb.edu>
- Components:
  - Administrative core
    - Coordinates and facilitates the preparation of all paperwork required for GCRC and CORHIS.
    - Provides step-by-step protocol initiation, guidance and support.
  - Biostatistical core
    - Provides consultation for:
      - Experimental design
      - Sample size/power calculation
      - Statistical analysis
  - Informatics and Data Management core
    - Creates websites to manage clinical research
    - Offers secure data management assistance in database and forms design, data storage, and computer lab facilities
    - Supplies computer training and consulting
  - Recruitment and Retention core
    - Assists investigators in the recruitment of minorities, women and children.
    - Assists with defining demographics following N.I.H. guidelines.
  - Nursing core
    - Assists in implementation of research protocols
    - Develops flow sheets, physician orders, etc.
    - Collects data and samples from various sources and locations for investigators
    - Obtains consent, vital signs and pertinent data from patients
    - Experienced in diverse nursing specialties: pediatrics, geriatrics, med/surg., pharmacokinetics and research certifications
  - Core lab
    - Nutritional Assessment
    - Analysis of Stable Isotopes by Mass Spectrometry
    - Analysis for Hormones and Substrates
    - Sample Collection and Processing
- Dr. Sharon Nachman, Office of Clinical Trials
  - What is new about the Office of Clinical Trials:
    - New director and staff
    - New objectives
      - Work plan
      - Countable measures of success
    - New web site
    - Compliance plans
    - Networking plans
  - Web site
    - <http://www.osa.sunysb.edu/octs/>
    - Redesigned site
    - For Patients:

- [FAQ](#)•[Glossary](#)•[Resources](#)•[Active Clinical Trials](#)•[Search Trials](#)
- For Investigators:
  - [Guidelines & Forms](#)•[Resources & Tools](#)•[List Your Study](#)•[Education & Training](#)•[Investigator's Network](#)
- For Sponsors:
  - [Industrial Partners](#)•[Patient Demographics](#)•[Contact Us](#)
- Objectives of the Office of Clinical Trials
  - Primary Objectives:
    - To identify research opportunities from pharmaceutical sponsors and match them with SB University faculty investigators
    - To connect with Contract Research Organizations (CROs) to identify opportunities
    - To mentor both junior and senior faculty to develop clinical trials expertise
    - To strengthen the link between the Office of Clinical Trials and the OSP/OVPR at Stony Brook
    - Clinical billing compliance
- Steering Committee
  - Members from clinical departments
    - Medicine
    - Anesthesia
    - OB/GYN
    - Psychiatry
    - Neurology
    - Emergency Medicine
    - Radiology
    - IRB, RF, compliance
- Database
  - To develop a database of patients (with attention to underlying medical conditions) entering all portals of care at Stony Brook
  - Clinical trials intranet
- Office of Clinical trials-Functions
  - All pharmacy studies will pass through office
  - We will confirm compliance with IRB, contracts, billing issues
  - Mentor faculty
  - Other services as deemed appropriate by the Dean
- Compliance
  - Contracts
  - Check list
  - Tracking patients
  - Billable services vs. clinical trial services
  - Tracking bills
  - Double dipping
- Contract check list
  - All contracts must be submitted to the OCT for review before going to the OSP
  - Standardization of all contracts
  - All studies must have attached check list for contract
- Keeping track of patients
  - Intranet system
  - Patient name, MRN, study entry and exit date

- Department
  - Division
  - Trial name
  - Second encounter number for research
- Work in progress.....
  - Moving a bill from point of entry
  - Unbundling of bills
  - Discounted Research costs
  - Labs
  - Procedures
  - Radiology
  - Etc.
- For more information, please contact us at:
  - The Office of Clinical Trials  
Level 4, Deans suite  
Health Sciences Center  
Stony Brook University  
Stony Brook, NY 11794-8430  
Phone: (631) 444-1217  
Fax: (631) 444-6148  
E-mail: [octs@osa.sunysb.edu](mailto:octs@osa.sunysb.edu)
- Ms. Judy Matuk, IRB Director
  - Office of Research Compliance (ORC)-Human Subjects Division
    - Liaison between the IRBs, Investigators, and Outside Entities
  - **IRBs review research...**
    - “A systematic investigation including research development, testing and evaluation designed to contribute to generalizable knowledge” (OHRP)
    - “any experiment that involves a test article and one or more human subjects” (FDA)
  - **Involving Human Subjects...**
    - The actual human being, and/or
    - Human tissue, and/or
    - Human data
  - Important facts regarding Human Subject Research at SBU
    - 1. The IRB membership comprises many types of individuals, including your peers (SBU faculty) and the off-campus community, including your patients.
    - 2. IRBs review activities that they are legally obligated, and ethically obligated, to review.
    - 3. Money is no object. Literally. Federally funded, Industry funded, dep’t funded, NOT funded. Doesn’t matter. All activities are reviewed equally, and held to the same high standards.
    - 4. The ORC and the IRBs work together. There is constant communication to maintain the (difficult) balance between protecting human subjects, and facilitating legally and ethically compliant research.
    - 5. Similarly, the IRBs (through the ORC) and the investigators work together to maintain that balance as well.
  - 3 Possible Routes for IRB review at SBU
    - SBU’s Committees on Research Involving Human Subjects (CORIHSA, CORIHSA)
      - Identical Charge (not just social/behavioral or just biomedical)

- Each has one deadline and meeting date per month
- The Commercial IRB Option:
  - Chesapeake Research Review, Inc. (CRRRI)
  - (Option is available only for industry-sponsored, industry-initiated studies)
- The National Cancer Institute Central IRB Option:
  - NCI's Pediatric and Adult Central IRB's  
(option is available for certain oncology group trials: ECOG, GOG, COG, NSABP, etc.)
- **ORC retains responsibility for compliant conduct of the activities regardless of the IRB used.**
- The 'application route' you take depends on the level of risk and federally-determined review category
  - If no foreseeable risk and fits into an exemption review category, the 'exempt' application is completed.
    - Review conducted by the 'Institution' (ORC staff)
  - If minimal risk, and fits into an expedited review category, the 'full' application is completed.
    - Review conducted by 2 IRB members, by mail
  - If the activity doesn't fit into either of the above, full committee review is required.
    - 2 deadlines per month
    - [www.stonybrook.edu/research.HSG/HSGsec2.html](http://www.stonybrook.edu/research.HSG/HSGsec2.html)
- When is the activity NOT research involving human subjects?
  - Clinical Practice is not research involving human subjects
  - Case Reports are not research involving human subjects
  - Hospital-endorsed QA/QI activities using patient data are not research involving human subjects (as long as they do not meet the definition of research)
- Oversight Responsibilities
  - Who is monitoring SBU to make sure we are doing clinical research in a compliant manner?
    - At the federal level: OHRP, FDA
    - At the local level: IRBs, ORC
    - At the 'public' level: our community (the source of our research volunteers)
  - Who is responsible for ensuring that SBU gets a 'clean bill of health'?
    - The IRBs
    - The ORC
    - You and your study staff
- Links to important sites
  - Website for Research Involving Human Subjects-GENERAL
  - <http://www.stonybrook.edu/research/humans/humansubjects.html>
  - Policies and Procedures for Investigators
  - <http://www.stonybrook.edu/research/humans/humansubjects.html#campol>
  - Applications (including those for HIPAA)
  - <http://www.stonybrook.edu/research/humans/hsforms.html>
  - Deadlines, Meeting Dates
  - <http://www.stonybrook.edu/research/humans/irbsched.html>
  - IRB Membership (CORIHSa, CORIHSb)
  - <http://www.stonybrook.edu/research/humans/irbmembers.html>

- Mr. Ivar Strand, Sponsored Programs Director
  - The Office of Sponsored Programs (OSP)
    - Submits formal grant applications on behalf of faculty (OSP Coordinators)
    - Negotiates contracts with industry, all branches of government and with non-profit organizations (OSP Contract and Grant Administrators)
    - Dedicated individuals for pharmacy-sponsored and initiated clinical trials as well as NYS contracts
    - Staff Outreach Office in SOM (OSP Coordinator)
  - How Do I Learn about Opportunities for Clinical Research?
    - The Office of Clinical Trials
    - The OVPR Resource Center
      - -Funding bulletin, COS, deadlines calendar, funding announcements (all submitted via SPOC)
    - The Associate Vice-President for Research, Michael Hadjiargyrou, Ph.D.
      - -Multi- and interdisciplinary endeavors
    - The Office of Scientific Affairs
      - -Targeted Research Opportunities
  - New Administrative developments
    - Federal implementation of Grants.gov
      - -OSP/Research Resources Center conducted 6 training sessions for 75 individuals, including MAC users
      - - NIH mandating electronic submission of R01 proposals due 2/5/07
    - COEUS Project
      - - Proposal development set for deployment May '07
      - - IRB, COI, proposal tracking modules set for later this year
      - - Ultimately interface with RF's Oracle financial system
    - Implementation of a 5 day internal deadline by OSP
  - The Office of Technology Licensing and Industrial Relations (OTLIR)
    - Reviews all New Technology Disclosures for commercialization potential for the campus
    - Negotiates all Material Transfer Agreements for the campus
    - Note a series of articles authored by Chester Bisbee, Director, OTLIR
    - <http://sunysb.edu/research/otlir/IPbasics.html>
    - IP provisions in sponsored research agreements are coordinated between OTLIR and OSP
  - Administration of K (Career Development) Awards
    - Involve mentor-based translational research
    - Stipulation to spend 75% of time on research area
    - These awards are scrutinized closely by the federal government
    - It is vital that recipients be released from clinical duties in order to conduct project
    - Strong record keeping is mandatory
  - Helpful links
    - OVPR Research Resources Center:
      - <http://www.stonybrook.edu/research/fndopp/index.html>
    - Office of Scientific Affairs:
      - <http://www.osa.sunysb.edu>
    - Associate VP for Research:
      - <http://www.stonybrook.edu/research/workgroups.html>

- Office of Sponsored Programs:
  - <http://www.stonybrook.edu/research/spo/index.html>
  -
- Ms. Leigh Gentilcore, Clinical Trials Contracts
  - CDA (Confidential Disclosure Agreement) received/reviewed and executed by OSP
  - Sponsor/CRO (Contract Research Organization) forwards protocol and/or site questionnaire
  - PI/Dep't determine feasibility of study
  - Sponsor sends draft Clinical Trial Agreement and Budget to PI
  - Documents forwarded to OSP and OCT (Office of Clinical Trials)
  - Pre-Award process was described with flow diagram.
  - Master Clinical Trial agreements
    - GlaxoSmithKline
    - Eli Lilly
    - Amgen, Inc.
    - Novartis Pharmaceuticals Corp.
    - Merck & Co., Inc.
    - Purdue Pharma L.P.
    - Bayer Corp.
    - Eisai Medical Research Inc.
  - Budget information to consider
    - Indirect Cost Rate: 25%
    - IRB Fees:
      - a) Stony Brook: \$2,250
      - b) Chesapeake (CRR): \$2,450 (approx), plus SB institutional fee: \$750
    - Non-refundable start up fees:
      - \$2,000 (approx)
      - OCT budget review fee: \$250
      - OCT preparation of IRB application \$300 (optional)
  - Helpful links
    - Clinical Trial Fact Sheet:
      - <http://www.stonybrook.edu/research/spo/clin-trial-faq.html>
    - Clinical Trials Process Flowchart:
      - <http://www.stonybrook.edu/research/spo/ClinicalTrialsFlowchart.html>
    - 4 pg form and CID:
      - <http://www.stonybrook.edu/research/forms/campfrms.html#spoproject>
    - Office of Clinical Trials:
      - <https://www.osa.sunysb.edu/octs/welcomeInvestigator.jsp>
- Dr. Wadie Bahou, Vice Dean for Scientific Affairs
  - Dr. Bahou commented that the CTSA is an absolutely critical initiative for the entire University.
  - Hopefully faculty will take advantage of the extensive infrastructure to support clinical research at SB.
  - Research design incubator
    - Provide support for faculty to initiate research
    - Initiative through the Dean's office
  - Large scale bioinformatics support initiative
    - Offers support team to assist investigator
  - The OCT has expanded nicely and helps address short-term personnel issues.



- Nurse practitioners and support staff to assist investigators
- Core support
  - Tremendous core facilities
  - Basic science core- get technical support
  - Proteomics core- instrumentation grant for next-generation mass spectrometer has been funded
- Dr. Bahou commented that he is very excited by the ability to move forward with electronic grant submission, as it has been very frustrating to get all of the requisite signatures on paper forms. We have identified problems and are moving forward to in expeditious fashion.

#### IV. Faculty Senate Retreat

**Dr. Williams**

- Dr. Williams, Vice Dean of Academic and Faculty Affairs ,reported on 2 issues:
  1. The Faculty Retreat on Education will take place on February 10<sup>th</sup> at Sunwood
    - **The agenda for the retreat is as follows:**
      - 8:00 -- 8:30 Breakfast, group planning, introductions
      - 8:30 -- 10:00 Impediments & opportunity when implementing a competency based curriculum
        - Stephen Leapman, MD and Paula Wales, EdD
        - Educational Affairs, Indiana University SoM
      - 10:15 -- 11:15 Group Discussions
        - Assessment of Competencies
        - Integration of Competencies
        - Teaching to Competencies
        - IT and Competency-based Education
      - 11:15 -- 11:45 Reports
      - 11:45 -- 12:00 Summing up
      - 12:00 End
      - Please RSVP to Heidi Campani (4-3084) if you are planning on attending.
  2. MUSIC IN THE HSC-A NEW CONCERT SERIES
    - A newly organized concert series will start on Thursday, January 25, 2007 at 4:30 pm.
    - It will take place in Lecture Hall ONE, HSC Level 2 and is titled:THE ART OF THE PIANO TRIO
      - Katie Hyun, *Violin*
      - Jonathan den Herder, *Cello*
      - Sophie Patey, *Piano*

#### V. Report of President's Blue Ribbon Commission

**Dr. Priebe**

- Dr. Priebe has asked President Kenny to report to the Senate on the Blue Ribbon Commission report. This report should take place at the March 27<sup>th</sup> plenary session of the Faculty Senate.

#### VI. Departmental Faculty Senate Elections for 2007-2009

**Dr. Priebe**

- Dr. Priebe reminded the Faculty Senators to request their respective departments to submit their department nominations for SOM Faculty Senators.
- Nominations for Faculty Senate President and Secretary will also be needed.

#### VII. New Business

- No new business discussed.
- The next Faculty Senate meeting will be **Tuesday, March 27<sup>th</sup> at 5pm in LH 2.**
- The meeting was adjourned at 6:30 pm.