

**Minutes of the January 2006 Faculty Council Meeting**  
**Tuesday, January 3, 2006, 5 PM**  
**Hugh Hill Conference Room, R1-106**

**Officers Present:**

President - Fonda Davis Eyler  
President-Elect - David Paulus  
Secretary - Gregory Schultz

Vice-President - Lise Youngblade  
Past-President - Daniel Driscoll

**Department Representatives Present:**

Christy Carter - Aging & Geriatric Research  
Susan McGorray - Epidemiology  
Lei Zhou - Molecular Genetics  
Paul Reier - Neuroscience  
Sonal Tuli - Ophthalmology  
Laurence Morel - Pathology  
Hideko Kasahara - Physiology  
David Kays - Surgery

Jorg Bungert - Biochemistry  
Rebecca Pauly - Medicine  
Frank Bova - Neurosurgery  
Rodney Edwards - Ob/Gyn  
Parker Gibbs - Orthopaedics  
Tom Rowe - Pharmacology & Therapeutics  
Robert Zlotecki - Radiation Oncology

**Guests Present:**

Bradley Bender, MD, Associate Chair, Medicine  
Tom Walsh, PhD, Director of Sponsored Research  
Robert Vomacka, MA, Assistant Director IRB & IACUC  
Peter Iafate, PharmD, Director of Pharmacy (Shands at AGH), Chair Health Center IRB  
Marylou Behnke, MD - Pediatrics

1. President Fonda Davis Eyler called meeting to order at approximately 5:05pm.
2. Minutes for December 2005 were accepted with minor corrections.
3. Announcements, Reports, and Old Business:
  - a. Update on VA Policies and Pay - Bradley Bender, MD  
Handouts were given - [Physician & Dentist Pay Bill Overview](#)  
[Final Approved Pay Ranges for Physicians & Dentist Effective January 8, 2006](#)  
[Physician & Dentist Base & Longevity Pay Schedule](#)
    - I. The current pay for VA physicians was established by law in 1991. In 1991 the pay was fairly competitive, but has not changed since then and at the moment has lagged behind where practice and academics are currently.
    - II. As of January 8, 2006 the pay has been re-established and should be more simplified. The VA has until March 31<sup>st</sup> to make any salary changes that would be retroactive to January 8<sup>th</sup>.
    - III. There are 4 different tiers and most physicians will be in tier 1. Tier 2 is for Service Chief or Chief of an important function (director of MICU or Cath lab.) Tier 3 and 4 do not apply to any physicians at the VA, it is strictly for people who work at the network or central office.

- IV. Unlike in previous years we now have ranges per specialty. No person's total pay will decrease.
- V. The question was asked - What if the VA wants to pay a certain physician more than what UF is willing to pay them? This will be worked out on a case-by-case basis; the VA doesn't want to bid against the University. Also, the VA hopes to complement the CoM's Compensation Plan. A plan has been implemented that every two years the secretary will conduct two surveys to determine if the VA salary is competitive to outside physicians.
- VI. Additional detailed information is included in the handouts.

b. Report from IRB & IACUC - Tom Walsh, PhD; Robert Vomacka, MA & Peter Iafate, PharmD

Handouts were given - [Sample Questions from Faculty](#)  
[Answers to Sample Questions from Faculty](#)  
[Overview of Human Subjects Research and IRB Processes](#)

I. Q. When a study is already "approved in principle" except for minor typographical errors, why does it take weeks before sign-off on the study? It also seems like the approval process for study revisions that involve only minor corrections requires the same amount of time as revisions involving substantial changes. Can minor changes be expedited?

A. For any study that is approved with required explicit changes (spelling, formatting and/or text revisions), the PI should comply exactly with the requested changes. These can be administratively approved in the office without delay. If the PI does not make all of the requested changes, makes additional changes or disputes the findings of the reviewer then the revision must be forwarded for further review.

II. Q. Why does it take weeks from full-board approval until the official IRB stamp arrives, which is required before consenting of subjects can begin?

A. It is office policy that all approval letters are to be completed within 9 days of IRB meetings. Many PIs retrieve their approval letters directly from the office in order to avoid any campus mail delays.

III. Q. Why does it take so long for deliberation of federally funded multi-centered clinical trials (that have had critical review by NIH, IRB-approval by the sponsoring institution, and approval of a steering committee with data safety and monitoring board?) Some have complained that approval took so long that they were closed out of enrollment.

A. Why deliberate extensively for federally funded multi-centered clinical trials? NIH study sections review the science of a proposal without considering the ethics. The IRB is charged with ensuring that the science is sound and that the study complies with federal regulations for human subject research.

IV. Q. Why is the timeline for resubmitting revisions required by full-board review so soon that one can rarely get the paperwork back in to make the deadline for the next Board meeting? Someone wrote that the only way to speed up the process is to attend the meeting and take notes or required corrections, which still

may not make the deadline. It was noted that waiting for the IRB's official recommendations in writing can mean missing the next two Board meetings.

A. Why is the tabled timeline so short? We deliver review materials for each meeting to the reviewers one week prior to the meeting. We must have the tabled submissions in the office on Monday in order to prepare agendas and review materials for the following Wednesday (2 days).

V. Q. Can something be done to speed up the approval process of specific standardized tests and measures? For example, if such tests proposed for use by researchers are not in the IRB file and are proprietary, they must be purchased in order to get a copy to the IRB. This cannot be done until grant funds are released which cannot happen without IRB approval. If the study is approved and pending later submission of the tests, it requires a full-board review as if revisions have been made to the protocol. Could situations like this be expedited?

A. The IRB maintains a library of these standardized tests. If these tests are being utilized as part of the research then the IRB must review the test. The OHRP requires the IRB to review the content of all surveys and written tests that are part of an IRB Protocol. Additional standardized tests can be submitted to the IRB office to facilitate their use in new protocols.

VI. Q. Would it be possible to have an ombudsperson with authority, not to decide on approval, but to sign off on the cases where the IRB requirements do not apply to some studies or there are catches such as the above example? This might reduce unnecessary work of the busy board members.

A. Ombudsperson for Exempt Protocols. We will look into the feasibility of having someone in the office review exempt protocols. A QA process will need to be in place.

## VII. **WHAT CHANGES HAVE BEEN MADE TO IMPROVE THE PROCESS?**

- NIH Just in Time (Diminished cases needing IRB-01 review for grant submission)
- Western IRB (Commercial IRB has diminished cases needing IRB-01 review)
- Guaranteed release time from the Dean's office (Aids in recruiting committee members and providing for their time)
- Standardized tests (Can pick from menu of approved tests)
- Administrative corrections (Avoids return to PI for correction and resubmission)
- Move survey protocols to IRB-02 (Diminished cases needing IRB-01 review)
- Full Board corrections at meetings (Shortens approval time by weeks)
- IRB Training Courses (Improves quality of submissions)
- Letter generation tracking (Identifies points of delay)
- Accepting anyone's version of a protocol (i.e.: NIH, Drug Sponsor, COG, GCRC, etc) (Saves recreating a unique version for IRB-01)
- GCRC Harmonization (Avoids conflicting requests for changes)
- Tissue Bank, specific I.Q., and 2-page Informed Consent (Standardized format)

**Misconception** – expedited review does not necessarily mean faster review. It means that a single reviewer can approve the revisions. The workload of the

Chairs is large, an average of 175 items a week (Exempt & Expedited Protocols, Revisions, Adverse Events)

VIII. **Preventable Delays:**

- Paperwork is not on current forms (always download from the web!).
- Not all questions on the form are answered.
- Paperwork is not complete (e.g. missing last signed ICF at CR).
- Paperwork does not include 5 copies (please collate properly!)
- PI did not sign paperwork
- PI did not complete HIPAA training for Researchers.
- Clean copy of ICF, advertisement, etc not provided for stamping.
- Submission has the wrong IRB number on it.
- Submission is otherwise incorrect/inaccurate (compare enrollment numbers each year and make sure math is correct, make sure PI and title are correct, etc).
- Reply to Tabled, Explicit Change, and other Needs Reply letters a.s.a.p.
- Send representative to Full Board meetings to address issues, possibly make corrections.
- Deliver paperwork to office (campus mail can sometimes take several weeks)
- Pick up paperwork at office.

IX. Please remember there is a difference between the IRB office and the IRB Board. (see handout "Overview of Human Subjects...")

X. Additional detailed information given in handouts.

- c. The FC talked with the Dean regarding the call back of 3% from NIH. Some people with competitive and non-competitive renewals have only gotten 97% of what they had been promised before. There is no sure way of knowing if that will be restored or not. The Dean will be unable to support all of those who did not get all of their promised renewal. The Dean would like to try and provide some bridge money but an application process is required.
- d. The Compensation Plan Survey is ready and will be passed out between this meeting and the next meeting in February.
- e. The speaker for the Research Day Dinner was discussed and a motion was made and seconded to ask Manny Fernandez (Chair Board of Trustees) to speak.

4. New Business:

- a. There was no new business discussed.

5. The meeting was adjourned at approximately 6:55 pm.

*Minutes recorded by Rachel L. Dotson, Office Assistant.*