



GCRC NEWS

Inside This Issue

<i>From the Director</i>	1
<i>GCRC Core Lab</i>	1
<i>Scatterbed Research</i>	2
<i>User-Friendly GCRC</i>	3
<i>NCRR Opportunities</i>	4
~K23 Grant	4
~K24 Grant	5
<i>GCRC Courses</i>	6

Points of Interest

- UF GCRC awarded \$19 million from NIH
- DNA Bank plans underway
- GCRC announces new course in bioethics

FROM THE DIRECTOR

The life of a clinical or basic scientist is one of delayed gratification, and this fact of life certainly has been in evidence while the GCRC waited for its competitive renewal award notice and its new budget. Those have recently come to pass, and the Center has just embarked on the first year of a five-year cycle of funding to the tune of over \$19 million--the largest extant federal grant at the University of Florida. The award is a tribute to so many individuals throughout the University and Shands Hospital that it would take the entire newsletter to list them. However, particular thanks go to the Center's dedicated staff and to our faculty and trainees who utilize the GCRC and whose protocols reflect the high praise and meritorious review accorded them by the NIH. On these long coattails, yours truly recently became President-Elect of the national GCRC Program Director's Association.

With the new budget come new resources, some of which have been detailed in previous issues of the GCRC News. Several of these deserve renewed attention here, as do two GCRC-sponsored courses coming up this summer and fall for interested faculty and trainees.

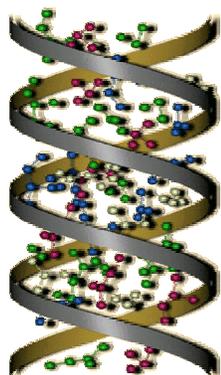
By the way, this new format for our newsletter reflects the creativity of Douglas Theriaque, Informatics Manager, and Nevil Parker, Program Assistant, of the GCRC.

WHAT THE GCRC CORE LAB MEANS TO YOU

The Sample Processing and DNA Bank portions of the Core Laboratory are in the process of becoming CLIA-certified. The Sample Processing Laboratory will be certified for the purpose of glucose, lactate, β -HCG, and routine urine analyses. This year, the lab will also implement a bar coding strategy to help anonymize samples that will also aid in triaging and storing samples of body fluids and tissues from subjects stud-

ied on the GCRC. This will be an important advance in providing sample identifiers that meet current federal guidelines for maintaining patient confidentiality and data integrity.

The DNA Bank, under the direction of GCRC Associate Director, Mark Brantly (brantml@medicine.ufl.edu), will be hiring an individual to assist in the isolation, coding, and storage of peripheral blood cells, serum, and



“Once the DNA bank is fully operational, we anticipate that the Center may obtain up to 1,500 samples per year.”

GCRC CORE LAB (CONT)

plasma for current and future genetic investigations. These samples will be linked to a brief, disease-specific questionnaire. All subjects (volunteers or patients) who enroll in a GCRC study will be asked by a Center representative to sign a consent form distinct from and in addition to the traditional Informed Consent that accompanies their enrollment in a specific study. The separate consent form will relate to the database questionnaire and blood products, all of which will be owned by the GCRC.

Investigators who wish to access this genetic information subsequently may do so, provided that their hypothesis-driven protocol is approved by the IRB and the GCRC Advisory Committee.

For example, Investigator A has a protocol to enroll patients with type 1 diabetes. Some of those subjects will provide consent (or assent) to donate a small amount of blood to the GCRC for the DNA Bank. A year later, Investigator B, who works principally in the area of hypertension, may wish to search for disease-specific genes using the stored leukocyte DNA from the type 1 diabe-

tes patients. Accordingly, Investigator B submits a protocol to the IRB and the GCRC's Advisory Committee that, if approved, provides him or her with the relevant patient databases and a portion of each subject's DNA.

Once the DNA bank is fully operational, we anticipate that the Center may obtain up to 1,500 new samples per year. With time, we hope this will provide a unique and diverse repository for genetic investigations.

We are also in the process of hiring a new laboratory director and a senior research chemist for the Biomedical Mass Spectrometry Laboratory of the Core Lab. These searches are being coordinated by Core Lab Director George Henderson (hendegn@medicine.ufl.edu) and by Mark Brantly. Filling these skilled positions will be essential to provide GCRC investigators with timely expertise in methods-development and application for the analysis of xenobiotics and naturally occurring compounds, from small molecules to proteins.

SCATTERBED RESEARCH

Associate Program Director, Des Schatz (schatda@peds.ufl.edu) heads this important resource. A scatterbed protocol is one that, either because of its complexity, the medical state of the subjects, or the logistical challenges of conducting the research, cannot appropriately be conducted in the GCRC per se. Accordingly, studies are undertaken, solely or in part, under the so-called "scatterbed" designation. This applies to protocols conducted in intensive care units, emergency or operating

rooms, imaging suites, off-campus clinics, and so on.

The GCRC has research nurses whose time is dedicated fully to scatterbed research. Moreover, scatterbed protocols may be benefited by support from the GCRC for ancillary laboratory costs, core laboratory analyses and biostatistical support. We are anxious to increase the number and diversity of scatterbed protocols, and interested individuals should contact Des.

MAKING THE GCRC USER-FRIENDLY

Anyone interested in learning more about the resources and opportunities associated with research and training in the GCRC should access its Web site (<http://www.gcrc.ufl.edu>). The site also provides step-by-step instructions on providing a GCRC protocol submission to the Advisory Committee. Investigators who wish to conduct GCRC research can avail themselves of one-stop

shopping, i.e., the same protocol submission, coupled with the IRB questionnaire and consent form, may be submitted to both the IRB and the GCRC Advisory Committee for review, either concurrently or consecutively.

For specific issues about proposed or pending GCRC studies, please contact the following individuals:

- Fiscal matters: Ann Coutu--Administrative Manager (265-8909; coutua@gcrc.ufl.edu)
- Nursing resources and inpatient/outpatient/scatterbed resource availability and scheduling: Maureen Surdez, RN--Nurse Manager (265-0680 x43717; surdemr@shands.ufl.edu)
- Biostatistical issues and data management: Doug Theriaque--Informatics Manager (265-0680 x06233; theriaqu@gcrc.ufl.edu)
- Federal Guidelines for Patient Safety and Data Monitoring: Barbara Frentzen, ARNP-- Research Subject Advocate (265-0680 x43715; frentzen@gcrc.ufl.edu)
- Mass Spectrometry Laboratory and general Core Laboratory questions: George Henderson, PhD (265-0680 x26193; hendegn@medicine.ufl.edu)
- DNA Bank: Mark Brantly, MD (846-0752; brantml@medicine.ufl.edu)
- Scatterbed research: Des Schatz, MD (265-0680 x20330; schatda@peds.ufl.edu)
- Gene therapy protocols: Terry Flotte, MD (846-2739; flottr@peds.ufl.edu)
- When all else fails: Peter Stacpoole, PhD, MD--GCRC Director (265-0680 x46791; stacpool@gcrc.ufl.edu)



Letter D—Physician holding a flask of urine. From the Isagoge Johanniti in Tegni Galeni by Hunayn ibn Ishaq al-'Ibadi, 809?-873 (known as Joannitius). Folio 42v. Oxford, 13th century. Online exhibition: Medieval Manuscripts in the National Library of Medicine: The Articella (<http://www.nlm.nih.gov/hmd/medieval/articella.html>)



For more information on the NCCR's funding opportunities, visit the Grants Information page at <http://grants1.nih.gov/grants/index.cfm>

OPPORTUNITIES THROUGH THE NATIONAL CENTER FOR RESEARCH RESOURCES

The NCCR is the NIH Institute that funds all eighty GCRCs. Its Director, Judy Vaitukaitis, has visited UF twice through the Center's GCRC Visiting Scientist Program. The NCCR's budget, currently over \$1 billion, supports several divisions, one of which is the Clinical Research Division that has a budget of over \$327 million. The new director of this division is Anthony Hayward, a pediatric immunologist formerly at the University of Colorado. Dr. Hayward oversees the three branches of the Clinical Research Division: the GCRC program; the Clinical Research Resources program; and the Career Development program.

The Clinical Research Resources branch supports two grant programs for groups of investigators, centers or other aca-

demically, with or without GCRC affiliation: The traditional **Shared Instrumentation Program** for one or more related pieces of equipment that cost between \$100,000 and \$500,000 and a new **"High End" Instrumentation Program** for purchases between \$750,000 and \$2 million. No institutional matching funds are required to be eligible for this latter program, and no indirect costs are provided for this one-year award. The NCCR budgeted \$10 million in FY '02 for this program. Most applications submitted involved equipment for imaging or mass spectrometry.

Further information on these instrumentation programs may be obtained through the NCCR's Website (<http://www.nccr.nih.gov/>).



K23 New Investigator Awards

The NCCR funds more K23 awards than any other NIH institute. These are five-year, mentored awards that provide up to \$75,000 per year salary support and up to \$25,000 per year in research-related expenses (supplies, equipment, travel). It is strongly recommended that physicians or other eligible trainees whose research at least partly involves the GCRC consider submitting their K23 proposal to the NCCR, whose study section is comprised of reviewers expert in and highly disposed toward funding patient-oriented investigations.

To do this, the potential applicant must undertake the following:

- Identify one or more mentors with an acknowledged track record in mentoring in the same or a related scientific field of interest. It is highly recommended that at least one of these individuals has current peer-reviewed federal funding in the general area of the applicant's research proposal.
- Obtain a written commitment of at least 75% protected time from the applicant's division chief and department chair.

- In addition to outlining a feasible research plan, describe his or her strategy for career development during the award period. It would therefore behoove the applicant to apply to become a fellow in the University's Advanced Post-graduate Program for Clinical Investigation (APPCI). This is a federally funded institutional grant under the K30 program that provides infrastructure support for trainees embarking on careers in clinical investigation. Among other benefits, it offers complete tuition support for graduate-level courses that are deemed highly desirable for K23 awardees. Indeed, K30 fellowship programs were designed, in part, to embellish the training and career development of federally-funded recipients of mentored research awards, such as K23s. Further details can be obtained by contacting Marian Limacher (limacmc@medicine.ufl.edu), the principal investigator for the APPCI.
- **At least** six months prior to the anticipated date of the K23 submission (June 1, October 1, February 1), the applicant and mentor(s) must contact either Peter Stacpoole or Larry Edwards, Chairmen of the GCRC Advisory Committee, about their interest in submitting the proposal to the NCR. The GCRC Advisory Committee will then select two or three individuals from its membership to help the applicant develop an appropriate application to the NCR. The GCRC portion of that application must be reviewed and approved by the entire Advisory Committee prior to submission of the grant, which can then be accompanied by glowing letters of endorsement by the Center's Program Director and Advisory Committee Chairman.

During the past fiscal year, the national success rate for NCR-fund K23 applications was approximately 46% (399 applications; 184 awards) and reflected over \$64 million in award dollars. For more information, access NCR Grants Information (<http://grants1.nih.gov/grants/guide/pa-files/PA-00-004.html>).

K24 (Midcareer Investigator) Awards

These are for established faculty who wish to engage in, and receive salary support for, mentoring in patient-oriented research. Candidates are usually within fifteen years of their specialty training, but exceptions are made. Awards are for five years and provide for up to 50% protected time, up to \$62,950 in salary support, and up to \$25,000 per year for research-related expenses. Dan Driscoll, a professor in the Division of Pediatric Genetics and a member of the GCRC Advisory Committee, and Mark Brantly, GCRC Associate Program Director, are UF's K24 recipients to date, and those interested in considering this opportunity should contact them.

During the last fiscal year, the NCR provided over \$23 million to fund 45% of the proposals received (128 applications; 58 awards). For more information, access NCR Grants Information (<http://grants1.nih.gov/grants/guide/pa-files/PA-00-005.html>).

Important Reminder!

Publications resulting from research conducted in part or wholly on the GCRC should include the acknowledgement: **Supported in part by General Clinical Research Center grant RR00082.**

“Physicians or other eligible trainees whose research at least partly involves the GCRC [should] consider submitting their K23 proposal to the NCR, whose study section is comprised of reviewers expert in and highly disposed toward funding patient-oriented investigations.”

GCRC COURSES

Our new course, Ethical and Policy Issues in Clinical Research, “provides the requisite educational information for any individual who wishes to be certified under current federal guidelines in patient-oriented research.”

During the first two weeks of October, the GCRC will sponsor its sixth annual **Science of Clinical Research (SCR)** course (GMS 6181). This one credit, graduate level course—the first required course in the APPCI curriculum—is open, at no charge and on a first-come-first-served basis, to fellows and faculty of any clinical department in the Health Science Center who may be interested in pursuing a career in clinical research. The SCR provides a broad overview of various topics relevant to the conduct of clinical research. It consists of three-hour sessions that meet five days a week for two weeks. Sessions are headed by a diverse group of senior UF faculty, and a syllabus is provided. Some time during mid to late summer, the GCRC will announce the forthcoming SCR course to the Health Science Center community and will provide ample opportunity to enroll in the course, either for credit or through audit. In addition to offering the course at no charge, the GCRC even provides snacks to maintain blood sugars and cognition!

This spring, we inaugurated a new

course entitled **Ethical and Policy Issues in Clinical Research** (GMS 6931). This course, for which two graduate credit hours may be obtained, was developed by Barbara Frentzen, the GCRC's Research Subject Advocate, and Bill Allen, Professor of Bioethics, Law and Medical Professionalism. The course will be given annually and is currently offered on Monday, 9 to 11 a.m., in Room CG-56 and on Wednesday, 2 to 4 p.m., in Room C2-42. It provides the requisite educational information for any individual who wishes to be certified under current federal guidelines in patient-oriented research. Additionally, it can be taken to fulfill requirements for training programs in clinical subspecialties in which didactic coursework in issues pertaining to the ethical aspects of human and animal investigation are obligatory. Ethical and Policy Issues in Clinical Research is also a required part of the APPCI curriculum. Details about this course can be obtained by contacting Barbara Frentzen (frentzen@gcrc.ufl.edu).

(Program descriptions for last year's SCR course and the current bioethics course follow.)

GCRC Course Descriptions

The Science of Clinical Research: 2001 Course Outline

Course Introduction – Challenges and Opportunities for the Physician–Scientist (Terry Flotte)

- Goals and overview of course – Terry Flotte
- Integration with UF's Advanced Postgraduate Program in Clinical Investigation – Ron Marks
- Perspective of a junior investigator – Jeffrey Skimming
- Description of student project – Ron Marks

Grants and Grantsmanship, Part 1 – Where the Money Is and How to Keep It (Frederick Southwick)

- Alternatives to NIH – Michele Tennant
- Funding opportunities for junior investigators – Frederick Southwick
- GCRC-based research and awards – Larry Edwards

Grants and Grantsmanship, Part 2 – How and What To Write (Frederick Southwick)

- Perspectives of a medical college dean – Kenneth Berns
- Elements of good writing – Ed Block
- Optimizing chances for an award and its renewal – Frederick Southwick

Study Design and Analysis in POR, Part 1 – Clinical Trials (Alan Hutson)

- Types of trials and protocol development – Alan Hutson
- Blinding and placebos – Alan Hutson
- Study design – Alan Hutson
- Multiple significance testing – Alan Hutson
- Randomization – Alan Hutson
- Sample size/power – Alan Hutson

Study Design and Analysis in POR, Part 2 – Clinical Trials (Alan Hutson)

- Intention to treat analysis – Alan Hutson
- Missing data – Alan Hutson
- Diagnostic accuracy – Alan Hutson

Study Design and Analysis in POR, Part 3 – Observational Studies (Ron Marks)

- Cohort studies – Ron Marks
- Case-control, cross-sectional studies – Ron Marks
- Causality, evidence-based medicine – Ron Marks
- Epidemiological case studies – Judy Lew

Statistical Methods in Data Analysis in POR (Ron Marks)

- Overview of statistical methods – Ron Marks
- Introduction to Web-based research approach to clinical research – Ron Marks

Federal Guidelines and Scientific Integrity in POR – Rules to Know Up Front (Peter Iafrate)

- IRBs and informed consent – Peter Iafrate
- Data and safety monitoring for clinical trials – Barbara Frentzen
- Gender and minority representation and “ownership” of human tissues and fluids – Barbara Frentzen
- FDA governance of new product development – Susan Beltz

Special Topics in POR – Diversions from the Standard Paradigms (Mark Brantly)

- Structure and function of NIH – Kirsten Madsen
- How grants are triaged and reviewed – Kirsten Madsen
- Biotechnology – Shelly Schuster
- Pharmacogenetics – Julie Johnson
- DNA arrays – Henry Baker

Grants and Grantsmanship, Part 3 – How and What to Write (Peter Stacpoole)

- Critique of student POR proposals – Mark Brantly, Alan Hutson, Ron Marks, Peter Stacpoole
- Critique of course – Peter Stacpoole



Vermont MS.2 – Illustrations from an Italian Herbal from 1500. Division of the Louise M. Darling Biomedical Library, UCLA. Cataloged in the Graphical Index of Medieval Medical Images (IMMI). [<http://www.library.ucla.edu/libraries/biomed/his/immi/immi.html>]



**General Clinical Research
Center**

Box 100322
JHMHC
University of Florida
Gainesville FL 32610

Phone: 352-265-8909
Fax: 352-338-8910
Email: coutua@gcrc.ufl.edu

COURSE DESCRIPTIONS (CONT)

Ethical and Policy Issues in Clinical Research: 2002 Syllabus

- | | |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| <u>Class 1: May 13</u> | <ul style="list-style-type: none"> • History of Research Ethics • Basic Ethical Principles |
| <u>Class 2: May 15</u> | <ul style="list-style-type: none"> • Overview of Major Issues in Human Subjects Research • Ethics and the Scientist |
| <u>Class 3: May 20</u> | <ul style="list-style-type: none"> • Epidemiological Research • Genetics • Tissue Banking |
| <u>Class 4: May 22</u> | <ul style="list-style-type: none"> • Research Involving Vulnerable Subjects |
| <u>Class 5: May 27</u> | Holiday—No Class |
| <u>Class 6: May 29</u> | <ul style="list-style-type: none"> • Clinical Trials |
| <u>Class 7: June 3</u> | <ul style="list-style-type: none"> • Research and the Drug/Device Approval Process |
| <u>Class 8: June 5</u> | <ul style="list-style-type: none"> • Research Involving Women and Members of Minority Groups |
| <u>Class 9: June 10</u> | <ul style="list-style-type: none"> • Research on Animals |
| <u>Class 10: June 12</u> | <ul style="list-style-type: none"> • Managing Conflicts of Interest |
| <u>Class 11: June 17</u> | <ul style="list-style-type: none"> • Ownership of Data and Intellectual Property |
| <u>Class 12: June 19</u> | <ul style="list-style-type: none"> • Authorship and Peer Review |

**We're on
the Web!**
[www.gcrc.
ufl.edu](http://www.gcrc.ufl.edu)