An Update from the Associate Dean for Clinical Research

Larry W. Moreland, MD

January 2006 Newsletter Volume 2, Issue 1

From the desk of the Associate Dean:

First, I want to give a brief update on the NIH Clinical and Translational Science Award (CTSA) that is being prepared for submission at the end of March. This massive institutional effort will result in the formation of the UAB Center for Clinical and Translational Science (CCTS). When funded, this Center will bring in approximately $10 million per year and will span at least 10 schools. Planning groups and the Key Function Leaders (noted below) are working hard to produce a successful application. I encourage you to be as responsive as possible as we request information to finalize our submission. Though CTSA awards will eventually replace all existing GCRCs, the GCRC Clinical Research Feasibility Funds (CReFF) are still available this year. They support junior faculty involvement in clinical research or senior faculty who are changing career paths and proposing to conduct clinical research. More information and deadlines can be found toward the bottom of this page.

Finally, the NIH has developed a new award mechanism, the Pathway to Independence (PI) Award (K99/R00), which is designed to facilitate receiving an R01 award earlier in an investigator’s research career. More information and a link to this RFA can be found on page 2.

Update on CTSA Application

We have finalized the components of the application, and will submit 12 key functions associated with the UAB CCTS. These functions (and their leaders) are listed below.

- Development of Novel Clinical & Translational Methodologies (Tim Garvey, MD)
- Pilot and Collaborative Translational and Clinical Studies (Peter Emanuel, MD)
- Biomedical Informatics (Bruce Korf, MD)
- Design, Biostatistics, and Clinical Research Ethics (George Howard, DrPH)
- Regulatory Knowledge and Support (David Warnock, MD)
- Participant and Clinical Interactions Resources (David Kimberlin, MD)
- Community Engagement (Max Michael, MD)
- Translational Technologies and Resources (Lisa Guay-Woodford, MD)
- Research Education, Training and Career Development (Richard Kaslow, MD)
- Drug Discovery and Industry Relations (Eric Sorscher, MD)
- Outcomes Research (Catarina Kiefe, MD, PhD)
- Minority and Health Disparities Research (Mona Fouad, MD)

Work is currently being done to establish the organizational structure of the new center. The CCTS will have a traditional Institutional Advisory Committee and will make use of the newly established Council of Center Directors (COCD) – a group comprised of University-wide Center Directors. These two entities will ensure that the Center receives broad-based input and is able to streamline available resources. I will serve as Chair of the Executive Committee, with other members including Drs. Jay McDonald and David Kimberlin (Associate Directors), Dr. Etty Benveniste, and the elected Chair of the COCD.

Announcement for 2006 Clinical Research Feasibility Funds (CReFF)

The CReFF program is designed for junior faculty interested in clinical research or senior faculty conducting clinical research as part of a career change. This research should lead to submission of a competitive application to a major research funding agency (e.g., NIH). Funding does not require preliminary data, but GCRC resources must be utilized.
An applicant can request up to $20,000 for a one-year project period (7/1/06 – 6/30/07). Investigators may use these awards for laboratory, personnel, and patient-related costs; however, salary support will not be available for the PI. An additional year of funding may be available based on the research priority and progress reports. Applicants must have primary faculty appointments at one of the 12 UAB schools at the level of Instructor or higher and must be either US citizens or non-citizen nationals.

If interested, a letter of intent should be submitted addressing eligibility and including a brief description of the proposed project. Letters are limited to one single-spaced page with standard NIH type size and one inch margins. They should be submitted to me at the Pittman GCRC, MEB M907, 6909 no later than February 14, 2006. Applicants will be notified regarding eligibility to submit a full proposal. Guidelines are available at http://www.gcrc.uab.edu/application.asp. GCRC Clinical Investigator Fellowship Awards (CIFA) will also be available later this Spring; they will be announced soon.

New NIH K99/R00 Pathway to Independence (PI) Award
The NIH Pathway to Independence Award will provide up to five years of support in two phases. The initial mentored phase will provide support for salary and research expenses for up to 2 years for the most promising and exceptionally talented new investigators who have no more than 5 years of postdoctoral research training experience at the time of initial application or subsequent resubmission(s). This initial phase of mentored support will allow the candidate time to complete research, publish results, and bridge to an independent research position. As part of the application, the candidate must propose a research project that will also be pursued as an independent investigator during the second phase of the award. The candidate and mentors together will be responsible for all aspects of the mentored career development and research program. An individual may submit an application from an extramural or intramural sponsoring institution/organization that has a rich and extensive research program in the area of interest as well as the faculty, facilities and resources to support the proposed research endeavor. The individual must select an appropriate mentor with a track record of funded research related to the selected research topic and experience as a supervisor and mentor. The sponsoring institution must ensure that the candidate has the protected time needed to conduct the proposed research.

Following the mentored phase, the individual may request up to 3 years of support to transition, as an independent scientist, to an extramural sponsoring institution/organization to which the individual has been recruited. This support is to allow the individual to continue to work toward establishing his/her own independent research program and prepare an application for regular research grant support (R01). Support for the independent phase, however, is not automatic and is contingent upon being accepted by an extramural institution and the successful NIH programmatic review of the individual’s mentored phase of the award.

A brief comparison of the new award and several existing NIH training awards can be found in the table below. More information on the K99/R00, can be found at http://grants1.nih.gov/grants/guide/pa-files/PA-06-133.html.

Comparison of Select NIH Training Awards

<table>
<thead>
<tr>
<th>Award*</th>
<th>Degree</th>
<th>Mentor</th>
<th>Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>K01 Mentored Research Scientist Development Award (clinical or basic science)</td>
<td>Research or health-professional doctorate</td>
<td>Required</td>
<td>US citizen or lawfully admitted for permanent residence by the time of award; individuals on temporary or student visas are not eligible</td>
</tr>
<tr>
<td>K08 Mentored Clinical Scientist Development Award (clinical, not patient oriented)</td>
<td>Clinical doctoral degree</td>
<td>Required</td>
<td>US citizen or lawfully admitted for permanent residence by the time of award; individuals on temporary or student visas are not eligible</td>
</tr>
<tr>
<td>K23 Mentored Patient-Oriented Research Career Development Award (clinical, patient oriented)</td>
<td>Clinical doctoral degree</td>
<td>Required</td>
<td>US citizen or lawfully admitted for permanent residence by the time of award; individuals on temporary or student visas are not eligible</td>
</tr>
<tr>
<td>K99/R00 Pathway to Independence Award (clinical or basic science)</td>
<td>Clinical or research doctoral degree</td>
<td>First 1-2 years</td>
<td>US citizens and non-US citizens with the skills, knowledge, and resources to carry out the proposed research are invited to apply</td>
</tr>
</tbody>
</table>

*All provide support for 3-5 years, require at least 75% effort, and are available through multiple NIH Institutes (which have differing success rates).