New PHS 398 and 2590 Forms

NIH has released its 5/01 version of the PHS 398 and 2590 forms. After January 9, 2002, these forms will be mandatory. Until then, applicants have two choices:

• use the 4/98 version, following its instructions, or
• use the 5/01 version, following its instructions.

Some of the differences between the two PHS 398 versions are:

• The new 5/01 version allows four pages for each Biosketch, compared to three pages in the "old" modular format and two pages in the 4/98 standard format.

• In the 5/01 version, information on the inclusion of women, minorities and children is no longer part of the 25-page limit of the Research Plan.

• Within the Appendix, the 5/01 version allows applicants to include ONLY manuscripts that have been accepted for publication. The 4/98 version allows manuscripts submitted for publication.

Until the 5/01 version becomes mandatory, investigators may want to evaluate whether one of the two versions offers them strategic advantages in the review process.

Forms and the NIH Notice can be accessed at: http://grants.nih.gov/grants/forms.htm

Lane’s Research Funded

Dr. Pascale H. Lane, MD, a Nephrologist in the Department of Pediatrics recently received a $1,125,000, 5-year grant from the NIH to examine the role of sex steroids in the control of renal TGF-b. As early as the 1950’s it was observed that the duration of diabetes mellitus (DM) before proteinuria was dependent on the age of onset of DM. Patients who developed DM early in life developed proteinuria after having the disease longer than those whose DM occurred later in life. This phenomenon was attributed to pre-pubertal protection from nephropathy. Subsequent studies have confirmed that clinical complications are unusual before puberty, and that sexual maturation seems to accelerate nephropathy and retinopathy. Others have shown that lesions that occur with DM in the pre-pubertal kidney do not have the same structural or functional consequences that they do after sexual maturity. Male rats given streptozocin to induce DM before and after puberty show different renal structural responses. The classic renal and glomerular hypertrophy of DM is seen in adult rats but blunted or absent in pre-pubertal animals. These differences in renal hypertrophy correspond to differences in expression and production of transforming growth factor-beta (TGF-b), a growth factor that plays a major role in the development and progression of the kidney disease of DM. Sex hormones may influence renal TGF-b via the renin-angiotensin system, oxidative stress, or protein kinase C. In addition to better understanding the impact of puberty on the kidney in DM, these experiments may elucidate reasons why most kidney diseases, Continued on back.—Lane
To help faculty identify funding sources for their research and scholarly activities, the Office of Sponsored Programs Administration has subscribed to Community of Science (COS) an electronic database of more than 18,000 funding programs.

How to Access Community of Science

No passwords or login ID is needed. You can access a couple of ways:

- Enter web address: http://fundinggopps.cos.com/ or

Follow these steps

- Enter www.cos.com
- Select “services” (gold button at top)
- Select “funding opportunities” (link is within the text)
- Select “main search”

The Instructions button gives helpful information on designing effective searches and refining the search.

Submitted by Deborah Vetter
Sponsored Programs Administration

The Clinical Research Center would like to introduce our coordinators to you.

Donna O’Grady, RN came to us from the pediatric intensive care unit in September of last year. Her background with children has been invaluable in the pediatric studies not to mention the technical skills and attention to detail she has developed over the years.

Deb Parrish, MSN is a retired Major in the USAF who started in April. She has a strong background in intensive care nursing. Her ICU and organizational skills have been greatly utilized with 14 active studies currently ongoing. We have been very busy.

Group health plans and private insurers would be required to pay for certain clinical trial costs under “Patients’ Bill of Rights” legislation currently being considered by the U.S. Congress. However, the House of Representatives and the Senate disagree as to what types of FDA-approved clinical studies should be afforded coverage.

The Senate’s “Bipartisan Patient Protection Act” (S 1052) was co-sponsored by Sens. Edward Kennedy (D-Mass), John McCain (R-Ariz.), and John Edwards (D-N.C.) and passed June 29; would require group health providers and health insurance companies to pay for “routine costs,” such as blood tests and physician visits, associated with clinical trial participation. Clinical trials considered eligible for coverage under the Senate legislation include those approved and funded by the NIH and the departments of Defense and Veterans Affairs, as well as studies approved by the FDA and sponsored by the drug, biologics and medical device industries.

The House of Representatives is offering similar provisions for clinical trial coverage in one of its proposed patients’ rights bills (HR2315), but has suggested a more fiscally conservative approach to FDA research to include only those studies involving investigational cancer treatments.

A competing House bill (HR2563, co-sponsored by GOP moderates) mirrors the Senate bill and calls for coverage of all FDA-approved clinical trials, not just cancer-related research.

House Republican leaders postponed a vote on the patients rights bills rearing that they lacked the necessary votes to approve HR 2315-the bill favored by the Bush administration. The House and Rep. leaders were working to develop a compromise.

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including DM, affect men more severely than women.

“My work is an example of how a clinical observation can become a basic research project,” explains Dr. Lane. “I hope that better understanding a state of relative natural protection will lead to new treatments to prevent the kidney disease of DM. The ultimate goal of these studies is to bring something back to patients.”