



# NIH upDate

## National Institutes of Health upDate

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Welcome to our first issue of NIH upDate. This newsletter has been developed to communicate important, relevant changes underway at the NIH, as well as changes in internal administration that impact you and your research. We plan to publish and distribute this newsletter quarterly.

In addition to this newsletter, we also maintain an "NIH News and Events" web page, <http://www.etsu.edu/research/NIH.htm>. This web page is updated regularly so if you need near-real time information, please bookmark this page and visit it often. On this web page you can find up-to-date information about changes to grant proposal administration, new policies that impact PIs, and information about new initiatives at the NIH. There are also useful links on this web site that you can use to take you directly to frequently used resources such as forms, receipt dates, policy manuals, and the eRA Commons.



We hope you find this information useful. Please contact us via email: [research@etsu.edu](mailto:research@etsu.edu) if you have suggestions for items you would like to see included in future issues of this newsletter or on our web page.

### Special points of interest:

- The new ETSU Human Subjects federalwide assurance number is 00002703.
- There is a new Biosafety web page: <http://www.etsu.edu/research/biosafety.htm>.
- Indirect Cost Waiver Request forms are now required when a grant proposal budget does not include indirect costs (F&A). You can download the form from our web site <http://www.etsu.edu/research/forms.htm>.

## NIH Public Access Policy

As part of an effort to engage the public in medical research, the NIH recently implemented a public access policy to encourage scientific communication with the public. The policy requests and strongly encourages all NIH-funded investigators to make their peer-reviewed author final manuscripts available to other researchers and the public at the NIH National Library of Medicine's (NLM) PubMed Central (PMC) (<http://www.pubmedcentral.nih.gov>) immediately after the final date of journal publication. Authors are given the option to release their manuscripts at a later time, up to 12 months after the official date of final publication. NIH expects that only in limited cases will authors deem it necessary to select the longest delay period.

NIH is requesting that authors submit manuscripts resulting from 1) currently funded NIH research projects or 2) previously supported NIH research projects if they are accepted for publication on or after May 2, 2005. The policy applies to all research grant and career development award mechanisms, cooperative agreements, contracts, institutional and individual Ruth L. Kirschstein National Research Service Awards, as well as NIH intramural research studies. The policy applies to peer-reviewed, original research publications that have been supported in whole or in part with direct costs from NIH, but it does not apply to book chapters, editorials, reviews, or conference proceedings. Publications resulting from non-NIH supported research projects should not be submitted.

## New PHS 398 Form

The NIH has a new PHS 398 form, which as of May 10, 2005, has become mandatory. Grant proposals submitted using previous versions of the form will be returned to the PI. Please be sure you are using the 9/2004 version. There are many notable changes to the new forms including:

### Face Page:

- Title—Form field length has been increased to 81 characters.
- eRA Commons User Name field has been added. This data item is currently **optional**.
- Human Subjects Research box has been modified to include a new data element for Clinical Trials.
- The IPF option data field in block 9 has been eliminated.

### Form Page 2:

- Now 2 pages (Form Page 2 & Form Page 2-continued with 5 distinct sections—Description, Performance Sites, Key Personnel, Other Significant Contributors, and Stem Cells).
- Description/Abstract: Instructions have been added requiring the PI to succinctly (2-3 sentences) describe the relevance of the proposed research to public health. Plain language is suggested.
- Key Personnel Section: A field has been added for the eRA Commons User Name. This new data item is currently **optional**.
- Other Significant Contributors: This is a new field that allows the PI to identify individuals who have committed to contribute to the scientific development or execution of the project but are *not* committing any specified measurable effort. (Biographical sketches will be required for these individuals; Other Support information will not be required.)
- Human Embryonic Stem Cells: Previously embedded in the Description, information pertaining to projects that involve human embryonic stem cells has now been requested as a separate form field. A link to the Human Embryonic Stem Cell Registry is provided.

### Form Pages 4 and 5:

Budget pages have been modified to implement the broader application of the policy on Direct Cost Limitations (e.g., excluding consortium/contractual F&A costs when determining eligibility for any application with a direct cost limitation). Specifically, the "Consortium/Contractual Direct Costs" budget row has been moved above the "Subtotal Direct Costs" line. Instructions have been revised to implement the new policy.

### Modular Budget Format Page:

The budget data fields have been modified to implement the new policy on Direct Cost Limitations. Specifically, users must now separate the Consortium F&A costs from the other Direct Costs. Instructions have also been revised to implement the new policy.

### Biographical Sketch Format Page:

A field has been added for the eRA Commons User Name. This data item is currently **optional**.

### Personal Data Page:

Applicants are now requested to provide only the last four digits of their Social Security Number. While providing this information remains voluntary, it is hoped that by limiting the data to only the last four digits, individuals will be more receptive to providing it. This vital information continues to provide the agency with accurate identification, referral, and review of applications as well as for management of PHS grant programs.

### Key Personnel Report Format Page:

The request for a Social Security Number is now limited to the last four digits.

### Checklist Form Page:

- A field has been added for "Change in Grantee Institution".
- Foreign Application: Two distinct options are now provided 1) Grants at Foreign Institutions or 2) Domestic Grants with Significant Foreign Involvement. This data area also includes a text entry section to list countries involved.

For more details about the changes, visit: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-006.html>

## New PHS 2590 Form

There is a new PHS 2590 form. For details regarding the changes to the form, please visit <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-007.html>

## eRA Commons

The NIH eRA Commons (Commons) is a Web interface where NIH and the grantee community are able to conduct their extramural research administration business electronically. ETSU is registered as an institution with the Commons and individuals can receive “accounts”. The term “account,” as used by the NIH Commons, is a personal account that an individual would use to log into the NIH eRA Commons. An account is identified by a unique combination of username and password. If you have an NIH grant, intend to submit a grant proposal to the NIH in the future, or if you assist faculty members in your department with their grant proposals and grant awards you should establish an account. Please contact Cynthia Hardin (hardinc@etsu.edu) to request one.

At this time, there are a number of features on the Commons that enable us to do our NIH business electronically. These include: viewing the status of grant proposals as they travel through the review process, viewing an individual's grant history, downloading Notice of Grant Award documents, submitting requests for no-cost extensions of grant awards, submitting progress reports, and submitting just-in-time information.

Each type of user has access to different functions of the Commons. For example, the “PI” can view his or her own grant proposals and grants and upload some forms such as progress reports or JIT information. The “ASST” is a person designated by the “PI” to assist him or her with certain responsibilities for data entry of the grant proposals and grants. The “AO” or administrative officials can assign accounts to users and view all institutional information. The “SO” or signing official is the person who signs all grant proposals and submits no-cost extension requests to the NIH. The signing official at ETSU is Dr. Michael Woodruff. There are several AOs in the ORPSA as well as in COM departments.

If you have not yet visited the Commons web site, we encourage you to do so. There is a user friendly tutorial and lots of links to help you. We also offer a workshop twice a year; one in the fall and one in the spring, to assist with the Commons. The web site is: <https://commons.era.nih.gov/commons/index.jsp>

**PLEASE NOTE: you cannot submit grant proposals directly to the Commons!!!! See next 2 stories for more details.**

## Electronic Proposal Submission

Earlier this year the NIH began accepting grant proposals electronically. The grant proposals are submitted by the PI to a “service provider” (see next story) and the service provider in turn sends the grant proposal to the NIH. Once the NIH has received the grant proposal, the receipt information is entered into the Commons. The signing official of each institution is then required to officially “submit” the grant proposal via the Commons Web interface.

At this time, the NIH is only accepting the following types of electronic grant proposals: RO1, RO3, and R21 mechanisms which include those seeking less than \$250,000 in direct costs in any one year and have a modular budget. These restrictions are likely to change in the very near future so please stay tuned.

We have not yet had anyone at ETSU submit a grant proposal electronically so we cannot give you any feedback about the process. We strongly advise anyone planning to submit an NIH grant proposal electronically in the near future to plan ahead, submit early and leave plenty of time to account for potential problems.

**Please remember that all electronically submitted grant proposals—to the NIH or other sponsors—need to be reviewed and approved by the appropriate individuals in advance—preferably 3-5 days before the deadline.**

## Service Providers

The NIH has designated six different “service providers” through whom one can submit a grant proposal to the NIH. Five of the six service providers are private companies. The services they provide vary as do the cost of using their service. For more details and a list of the providers, please visit: [http://era.nih.gov/Projectmgmt/SBIR/sbir\\_grants.htm](http://era.nih.gov/Projectmgmt/SBIR/sbir_grants.htm) We cannot recommend a specific service provider to you at this time. As PIs begin to submit grant proposals electronically, we hope to gather information from their experiences and share these with you in future newsletters.

The only advice we can provide you at this time about service providers is to **avoid at all costs** the sixth service provider, which is the federal government. Grants.Gov is a federally sponsored web site that is free to all who wish to find funding information or submit grant proposals. There have been a lot of problems to users from throughout the country who have tried to submit grant proposals electronically through Grants.Gov. In many instances PIs have been unable to submit their proposals before the deadline because of “glitches” in the system. Grants.Gov requires that the PI give the electronic files to the Sponsored Programs office, who in turn must upload and submit the grant proposal on behalf of the institution. If you must submit your grant proposal using this service provider, we require that you send your completed grant proposal to us at least one business week before the deadline. However, we do not guarantee it will be received by the NIH on time if you choose this option.

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([Goergen@etsu.edu](mailto:Goergen@etsu.edu)) and request to be added to the mailing list.**

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## ***FYI....***

- COM is still eligible to submit AREA grant proposals. However, this might change in the near future if total NIH dollars received exceeds \$3 million in 4 out of 7 years. This is based on the Federal fiscal year. The following is the total of NIH dollars received for last 8 fiscal years (FY): \$563,496 FY 96; \$1,069,415 FY 97; \$2,331,314 FY 98; \$2,156,991 FY 99; \$2,491,780 FY 00; \$3,137,095 FY 01; \$2,541,027 FY 02; \$3,534,857 FY 03. The FY 04 amount is not yet available, but likely will exceed \$3 million dollars. If this trend continues, we predict that after FY 05, the COM will no longer be eligible for AREA grants. ETSU's main campus will still remain eligible.
- Several staffing changes have occurred recently in the Human Research Protections Program. Janine Richardson has been appointed as the new Director of the Human Subjects Research Protection Program and Aracelis Vasquez has accepted the new IRB Coordinator position. Please join us in welcoming them to their new positions.
- Dr. Brunhilde Tober-Meyer will be retiring in June after 27 years of service as the Director of the Division of Laboratory Animal Resources. A reception in her honor will be held June 30 from 2-4 p.m. in Stanton-Gerber Hall (Bldg 178) on the first floor mezzanine area. Greg Hanley, Ph.D., D.V.M., has been appointed as the new Director. Dr. Hanley comes from Vanderbilt University where he has served as the Associate Director of Animal Care and Welfare.
- Dr. John Hancock will be stepping down as Chair of the University Committee on Animal Care (UCAC) in June. Dr. James Stewart (Biology) has been appointed as the new Chair of the UCAC.