

ALL ABOUT GRANTS

"Giving You the Competitive Edge!"

VOLUME XXI, ISSUE 6

M A R C H 2008

INSIDE THIS ISSUE:

OFFICE OF

SPONSORED
RESEARCH AND

PROGRAMS

Farewell and 2
Future SuccessBill Alter

New OSRP Staff 3

Research Coor- 3 dinators

Grant Proposals 4
Support

Training@OSRP: 4
Export Controls

Federal Database: Contracts and Grants

Responsible
Conduct of Research

NIH eSubmis-

2008 External 6 Funding Results

Project High- 6 lights 2008

The 7
Compliance
Corner

Credit Sharing Amendment - Indirect Costs Policy

New Credit Sharing Amendment to the Distribution of Indirect Costs Policy

The number of multiinvestigator proposals submitted increase each year. Up until now, grant and contract awards issued to the University for these projects have been credited primarily to the lead investigator. This included distribution of the appropriate portion of recovered indirect costs to the home unit of the lead investigator, as well as listing of the award for this home unit.

Beginning on **April 1, 2008**, the credit for externally-funded grants will be shared by those who are named as Principal and Co-Principal Investigators (PI & Co-PIs) on these projects.

This credit sharing will occur in two ways.

Distribution of Indirect Costs:
 In accordance with the Distri-

bution of Indirect Cost Policy, the originating college/division, and department/center/unit for the PI and Co-PIs will receive a portion of the recovered indirect costs.

The basis for this distribution will be determined by a "Project Credit %" assigned by these individuals on the Internal Approval Form (IAF) when a proposal is submitted through the OSRP. These percentages should be based on the level of creative and project related effort to be dedicated by these individuals. Also, to be considered is the responsibility and effort that will be required of the PI and his/her home unit to administer the grant.

As with other commitments to such projects, the department head and dean (VP for non-

- academic unit projects) will have to sign the IAF indicating their concurrence with the proposed credit-sharing prior to submission of the proposal.
- Reports of Awards: A grant
 on a project with a multi investigator teams will be re corded to the home units of
 the PI/Co-PIs with the award
 amount reflecting a percentage
 of the funding based on the
 Credit-Sharing % assigned by
 these individuals. However, a
 project like this will still be
 counted as a single award for
 purposes of the total count of
 externally-funded awards com ing to Missouri State.

Further information and examples of the impact of the Credit Sharing Amendment can be found on the Distribution of Indirect Costs Policy web site – http://www.srp.missouristate.edu/31102.h tm.

Revised Internal Approval Form - April 1, 2008

As of April 1, 2008, a new Internal Approval Form (IAF) will take effect for all submitted application forms for NSF, NIH and PHS agencies. Submission of an Internal Approval Form is required for all proposals seeking external funding to support University-based projects. Changes in federal government requirements necessitate revisions, along with the implementation of the Credit-Sharing Plan

that also is to be implemented on April I, 2008.

Assurances

The Public Health Service (NIH is a component) and NSF have new compliance requirements regarding assurances. The University is required to secure and retain a written assurance from the Principal Investigator (PI) and Co-Principal Investigators (Co-PI) prior to submitting an application While this

assurance is no longer required as part of the submitted application, it remains a compliance requirement. Therefore, we must retain a unique signature and date for each submitted application. This assurance must be available to the sponsoring agency or other federal officials upon request.

(see http://www.srp.missouristate.edu/4915.h tm). Continued on next page

Internal Approval Form - Revised! - continued...

Such an assurance must include at least the following certifications: (I) that the information submitted within the application is true, complete and accurate to the best of the Pl's and Co-Pl's knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the Pl's and Co-Pls to criminal, civil, or administrative penalties; and (3) that the Pl and Co-Pls agree to accept responsibility for the scientific conduct of the project including submission of required progress reports if a grant is awarded.

In addition, NIH and NSF also require grantee institutions and investigators to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." That subpart promotes

objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an investigator. The "Conflict of Interest" section of the IAF has been revised to comply with this requirement. This also will be required of persons in organizations to which subcontracts are to be issued.

Credit-Sharing

PI and Co-PIs are to determine the percent of the total credit for a project. This would include their creative input to the project, the time to be dedicated to the project, as well as the time and effort that

they and their administrative unit will dedicate to the administrative unit will dedicate to the project.

A space has been provided for each PI and Co-PI to insert the percent of the Shared Credit that should be assigned to them for a specific project. These percentages will be reviewed by department heads/supervisors and deans/VPs during the submission process for the IAFs'. Once an award is made, these percentages will be the basis for distribution of recovered indirect costs in accordance with the Distribution of Indirect Costs Policy (see www.srp.missouristate.edu/31102.htm). These percentages also will be used to assign credit of these awards to the PI/Co-PIs and their home units in monthly and annual reports of institutional funding.

Farewell and Future Success - Bill Alter

There comes a time when all of us must move on. My time has come as I prepare to retire from the University on March 31st. This marks the end of a 12 year journey which has enabled our team in the Office of Sponsored Research and Programs (OSRP) to assist scores of faculty and staff to achieve success in acquiring the funding needed to pursue their research and scholarly interests, as well as address the many educational and community service needs in our institution and community.

During this time, external funding for University-based projects increased from \$7.6 million in FY 1996 to over \$20 million in FY 2007. Progress to date indicates that FY 2008 will exceed previous totals. The majority of the credit for all of these successes belongs to the faculty, staff and administrators who put forth the extra effort it takes to be successful in the very challenging world of "grant-getting." In addition, the encouragement and incentives developed by the President, Provost, Vice President for Research and Economic Development and the Deans have resulted in a greater number of proposals being submitted this year than we have seen in the recent past.

I am grateful for having had the opportunity to work with an outstanding team in the Office of Sponsored Research and Programs. There are two critical assets that enable a service office like OSRP to be successful. The first is a knowledgeable and dedicated mentor, and **Frank Einhellig** proved to be invaluable throughout the years in guiding our efforts. The second key to success is the person "at the front desk."

Over the years, our office has been fortunate to have very capable folks to handle this task $-\$

Teresa Carl, Jenny Crews, Marina Zordell-Reed and now **Janene Proctor**. Due to the increasing interest in pursuing external funding, and the requirements for compliance with ever more complicated federal regulations, our staff has expanded.

Tracey Poston started as a graduate assistant and is now serving as the Associate Director and University Compliance Officer. As you know Tracey will be leaving later this spring to become the Director of Compliance at the University of Notre Dame. We wish her well in this new venture.

Marina Zordell-Reed is now serving as the ERA Coordinator and is leading the effort to implement the Grants Management System, as well as being responsible for electronic submission of proposals.

Bruce Richards also started as a graduate assistant, and is now serving as the Research and Instructional Design Coordinator. He provides information on funding opportunities to faculty and staff, has designed several online training programs, renovated our web site, and is editor of the All About Grants Newsletter.

Most recently, **Debi Bick** joined us as the Proposal Development Specialist to assist faculty and staff in developing competitive proposals.

Shannon Winstead started as an undergraduate student, and is now working as a part-time staff assisting Tracey in the compliance area.

Courtney Towe is our newest graduate

assistant, working with Janene in office administration.

Of course, our office is not alone in supporting folks who seek and receive external funding. Folks in the Office of the General Counsel, Graduate College, Grants and Contracts Accounting, Procurement, as well as in the departmental and college administrative offices have been outstanding.

Marlee and I will continue to be residents of Republic, and look forward to seeing you at future University events, and I hope that you all consider becoming active bicyclists. We wish success to everyone in the University community as you move forward in developing the leaders of tomorrow.

Bill Alter.

NOTE: Please join us for a Retirement Reception honoring Bill. Date: March 31, 2008; Time: 12:00 - 3:00 p.m.; Location: Carrington 422



Perks of an Active Bicyclist





nstitutiona Biosafety

The Institutional **Biosafety Committee** (IBC), reviews proposed research involving recombinant **DNA** techniques and other biohazards (i.e., infectious or venomous agents), consults with researchers on biosafety procedures, trains faculty, staff, and students involved in bio-hazardous research to obtain compliance with appropriate rules.

Bio-safety is a cooperative effort of the IBC, the investigators, and laboratory staff.

Contact the OSRP for further details.

http://www.srp.missouristate.e.edu/Biosafety.htm

Welcome New OSRP Staff Members

Welcome to **Deborah Bick**, OSRP Proposal Development Specialist.

Debi is a Missouri native from Trenton and Hannibal, but has lived in the panhandle of Florida since 1991. She has directed the Educational Opportunity Center, a federally funded TRIO program, at Pensacola Junior College since 1997. Prior to that she directed the Single Parents/Displaced Homemakers program. Among her most successful proposals were three EOC grants, and a newly funded TRIO Veterans Upward Bound program. She has also been the Executive Director of Douglass Community

Center in Hannibal, Mo., a program similar to the Kitchen in Springfield, and ALIVE, a multicity program in the St. Louis area serving those experiencing domestic violence. Debi is a graduate of the University of Missouri in Kansas City with a degree in sociology as well as a graduate degree in counseling and human resources development from Troy State University, northwest Florida region. She enjoys the creative elements of grant work, but understand its challenges as well.

Welcome to **Janene A. Proctor**, OSRP Administrative Secretary.

Janene joined the OSRP staff in August of 2007. In addition to administrative duties Janene will be involved in the processing of proposals and contracts, pre-award support, and acting as a liaison between the University and the Sponsors.

Janene began her career at MSU in 1998 as a student and worked part time in the Nursing Department while finishing her BS in Communication Sciences and Disorders. She later worked full time in the Public Safety Department. She is from the Springfield area and resides here with her husband Bob.

Research Coordinators: Roles and Responsibilities

As part of a renewed focus to provide greater involvement and support from Colleges, a group known as the Research Coordination and Advisory Committee (RCAC) has been created to assist and encourage faculty and staff to pursue external funding to expand the University's research, education, and public service activities.

The office of Sponsored Research and Programs has been tasked to provide coordination and assistance to the RCAC along with the Proposal Development Specialist who is assigned as the primary point of contact.

The primary responsibilities of the group is to;

- Assist faculty and staff in developing project concepts and identifying funding sources.
- Review and edit draft proposals and facilitate development of multi-unit proposals originating from the colleges.
- Assist the Proposal Development Specialist in identifying high priority funding opportunities.
- 4. Work with faculty and staff

- in implementing externally funded projects, and
- Serve on the Research Coordination and Advisory Committee.

It is hoped that the RCAC will be a conduit towards developing solutions to problems that impact faculty's research interest and involvement in externally funded programs and they will assist proactively the Institutional Official for Intellectual property in enhancing the faculty and staff efforts to develop and commercialize long-term inventions. See http://www.srp.missouristate.edu/47221.htm detailing the members of the RCAC.

NSF: Intellectual Merit



On October 1, 2007, the Grant Proposal Guide, as well as new funding opportunities issued after that date, incorporated the revised new Intellectual Merit criterion. Necessary changes were also made to the National Science Foundation (NSF) reviewer systems to incorporate the revised language.

This change came about as the NSF Board unanimously approved a motion to enhance support of Transformative Research at the NSF.

Additionally, the Board approved a change to the Intellectual Merit Review Criterion specified in Part I of the NSF Proposal & Award Policies & Procedures Guide.

The term "transformative research" describes a range of endeavors which promise extraordinary outcomes, such as: revolutionizing entire disciplines; creating entirely new fields; or disrupting accepted theories and perspectives.

On the other hand the term intel-

lectual merit describes how important is the proposed activity to advancing knowledge and understanding within its own field or across different fields.

All proposals received after January 5, 2008, will be reviewed against the newly revised criterion.

See http://www.nsf.gov/pubs/2007/ in 130/in 130.jsp for further details.

Support to Develop Grant Proposals



Proposal Development Fund:

Course Reassignment:

In recognizing the need to increase the opportunities for faculty and staff to pursue external funding to support research, education and service activities, the University provides the above assistance.

Two course reassignments per academic year will be available to each college for faculty to have quality time to identify, plan, prepare, and submit a proposal to an external

organization. These reassignments are contingent upon a college contributing one course reassignment. Once a proposal is submitted, the college or department will be reimbursed **up to** \$3,000 for the cost of the per course faculty(s) salary and fringe.

Travel:

University units will be reimbursed for **up to \$1,000** for the travel expenses of a faculty or staff member who visits a funding organization to enable them to develop a proposal. Reimbursement will be paid to the initiating unit once

the proposal is submitted. A request for reimbursement for expenses will be processed electronically using the Travel Fund form.

See http://www.srp.missouristate.edu/4912.htm

Equipment Matching Fund:

The University recognizes the need to acquire equipment for research and other scholarly efforts. Beyond the funds available within the academic units, the Equipment Matching Funds Program enables the University to commit up to 50% of the costs for equipment in a proposal submitted to a funding organization when matching funds are required.

Training@OSRP: Export Controls

The Office of Sponsored Research and Programs (OSRP) has established Training@OSRP, which is our eLearning (online) Portal Training Resource web site.

One such featured training is Export Controls which describes the regulation that seeks to prohibit the unlicensed export of specific information and technologies. Export Controls require prior approval for foreign nationals to access information, technologies and

materials, participate in research, and limit partnering with a foreign company, and/or prohibit sharing research with persons who are not U.S. citizens.

These controls may affect many aspects of research because the term "export" covers not only the shipment of information or materials to another country but also the release or disclosure of information or materials to foreign nationals on U.S. soil ("deemed export").

As an employee of Missouri State



University, your responsibilities may require you to be aware of export controls or simply as one who has questions about the export control federal laws.

The online training seeks to educate and inform all persons through the history and concepts of the Export Control regulations, providing exercises, case studies, and a short test that challenges your understanding of the materials. See http://www.srp.missouristate.edu/

www.srp.missouristate.edu/ ExportControl_Training.htm "Education is what is left after you've forgotten everything you've learned."

Albert Einstein

A Federal Database on Contracts and Grants

Beginning 2008, data on sub-awardees and subcontractors will be required to be posted on a public Web site, and that information will come from universities. This web site, http://www.usaspending.gov/index.php, is required by the 2006 law, the Federal Financial Accountability and Transparency Act (FFATA). FFATA calls for the creation by Jan. I, 2008, of a single, searchable database containing information on all federal grants and contacts.

This law seeks to direct attention to in-

creased transparency and accountability on the revenue side of federal fiscal operations. This database will allow the public to track the flow of federal funds down to the ultimate recipient.

What this means is that all grants above \$25,000 will need to state the name of the entity receiving the award, the award amount, the date of the federal award, the type of "transaction" (loan, cooperative agreement, contract, grant), the funding agency, the account or accounts from which the money is drawn, a brief descriptive title of the project,

the agency-assigned award number, the location of the entity receiving the award, the primary "performance location" where the majority of the work is carried out, the DUNS number of the entity, among other items.

This information will have to come from us and must be accurate, so that we can defend the information. A pilot was started in July 2007 and the creation of the database by January I, 2008. See http://www.grants.gov/assets/FFATAMemo2.pdf for further details on the required database information.

Responsible Conduct of Research



As part of its stated responsibility, the Office of Research Integrity (ORI) oversees and directs the Public Health Service (PHS) research integrity activities on behalf of the Department of Health and Human Services. One important effort is the promotion of integrity in PHS-funded research. ORI undertakes activities that supports and enhances educational programs in the responsible conduct of research (RCR). In an introductory document on

RCR, the ORI states that RCR is a

comprehensive overview of basic

rules of the ethical behavior ex-

pected for responsible research available for all PHS-funded researchers. In general terms, responsible conduct in research is simply good citizenship applied to professional life. As research and public support for the work increases, so does public scrutiny on responsible behavior and accountability from all concerned that ensures that researchers have clear obligations to conduct their research in a responsible manner.

To meet this need for responsible conduct of research, higher educational institutions begun to require their researchers to become educated and aware of the rules, regu-

lations and professional practices that define their work.

The ORI has placed on their web site educational resources that support the educational awareness on responsible conduct of research that has been written primarily for researchers and research staff engaged in research supported by the Public Health Service but is applicable to scholarly research in general.

The University of Miami CITI training course also has a RCR course that is available to institutions that use CITI for their human subjects training. See https://

www.citiprogram.org/default.asp.

Office of
Research
Integrity (ORI)

The Office of
Research Integrity
(ORI) promotes
integrity in biomedical
and behavioral
research supported by
the U.S. Public Health
Service (PHS) at
about 4,000
institutions
worldwide.

ORI monitors
institutional
investigations of
research misconduct
and facilitates the
responsible conduct of
research (RCR)
through educational,
preventive, and
regulatory activities.

See <u>http://</u> ori.dhhs.gov/

GRC: GrantSearch is Remodeled

The Grants Resource Center (GRC) has recently remodeled its GrantSearch platform to reflect changes to the interface and logic to better able greater number of relevant search results. While the previous search platform emphasized text search, the remodeled system will encourage the use of academic category searches making for more intuitive and stronger search categories.

The GRC database contains approximately 2,000 funding

opportunities for which higher education institutions are eligible to apply or serve as partners. About three-fourths of the opportunities are federal. When conducting searches for members, the GRC staff supplements national private opportunities contained in GrantSearch with more targeted local opportunities contained in the Foundation Center database.

The new search platform will be available to all member institutions and their faculty to perform their own searches for grant op-

portunities.

The new platform will become permanent by **April 10, 2008**. Training is being provided by GRC personnel. Contact Allyson Lords (lordsa@aascu.org) to schedule an appointment.



GrantSearch platform

Did You Know? NIH Reduces Error Correction Window

In their December 2007 general notices, the National Institutes of Health (NIH), announced that effective for 2008, they will reduce their "error correction window" (i.e. the time allowed after the submission deadline to address NIH system identified errors/warnings) from five (5) business days to two (2) business days for all electronically submitted grant applications with submission deadlines on or after January 8, 2008.

This change means that electronic applications will be considered "on-time" if all of the following criteria are met:

All required registrations must be complete prior to the initial submission.

Initial successful submission to Grants.gov must have a timestamp on/before 5:00 p.m. local time of the applicant organization on the receipt date.

Applicants must correct errors and/or warnings within two busi-

ness days following the receipt date (referred to as the "error correction window").

All application corrections must be in response to a system-identified error/warning (application submissions with additional changes may be refused).

If final submission is sent after the receipt date, a cover letter attachment must be included identifying the system-identified errors/warnings that have been corrected.

See http://grants/guide/notice-files/NOT-OD-08-018.html.

NSF Casts Wide Funding Net for Federal Budget FY2009

In a recent report from the Grants Resource Center (GRC), Program Consultant Meg Cantwell outlined NSF's requested budget of \$6.85 billion for FY2009 that would seek to "keep America's scientist and engineers focused on the furthest frontiers".

This funding push would work in two main areas.

- For institutions that receive NSF funding support, to continue to receive more funding support for FY2009.
- For institutions that had their proposals declined to see increased opportunities for funding based on the 14% increase for FY2009.

All institutions must seek to focus where NSF, in February 2008, intends to be in a decade as by that time the agency will see

their budget double to more than \$10 billion annually. See http://www.aascu.org/ofpopen/GW/09nsf.pdf

Within the requested amount, the agency has made requests for increases of between two and twelve percent in the interagency National Nanotechnology Initiative (\$397 million), Climate Change Science Program (\$221 million), Climate Change Technology Program (\$23.5 million), and Homeland Security (\$379.17 million) activities.

The type of applicant that the agency is looking to target are;

- Predominantly Undergraduate Institutions—<u>The Research Experiences for</u> <u>Undergraduates</u> and <u>Research in Undergraduate Institutions</u> programs.
- 2. Graduate Students—An additional 700

- students, for a total of 3,075, would be supported by a 30 percent increase in <u>Graduate Research Fellowship</u> funding.
- 3. World Citizens—The Office of International Science and Engineering would receive a 15 percent boost, for a total of \$47.4 million in support of international collaborations in any NSF-supported discipline, undertaken by researchers at any stage of their careers.
- Underrepresented Groups—The agency's collection of programs to broaden participation of women, minorities, and minority-serving institutions in STEM.
- Techies—In its second year, the foundation-wide <u>Cyber-enabled Discovery</u> and Innovation initiative would double its spending, to a level of \$100 million.

Project Highlights, YTD 2008



The University has so far submitted 167 proposals for support of University-based projects for YTD FY 2008 ending January 2008. So far, 89 awards were received – some of which are from proposals submitted during the previous fiscal year. The commitment of funds in these grants and contracts amounted to \$9.1 million. It should be noted that some of these awards were for projects that extended over more than one year, but the formal commitment for funds is only for the current project year of FY 2008.

Research:

Dr. Paul Deal, Assistant Director of the Learning Diagnostic Center.

Received \$17,370 from the National Alliance of Mental Illness (NAMI) to develop a new training program titled, the NAMI Signature Educational Program for Young Families, that will target parents and other caregivers of children and adolescents with mental illness. As part of NAMI educational program, an Evidence Based Practice (EBP) Designation must be obtained. This designation will be achieved by evaluating participants to determine increase in knowledge and identify any needed modifications to the curriculum. Results from this program will be used to refine and serve as a foundation for subsequent classes

Education:

Dr. Dale Law, Executive Director for the Viticulture and Enology Science and Technology Center (VESTA), Dr. Barry Gump and Dr. Stanley Howell, Per Course Faculty at the West Plains Campus, and Dr. Karl Wilker, Associate Research Professor of Agriculture.

Received an initial award of \$1,645,899 from the National Science Foundation to ensure that the VESTA Regional Center of excellence is established and sustained in a manner that addresses the needs of the Mid-America region grape and wine industry. The VESTA Regional Center of excellence will provide a knowledgeable and skilled workforce for the grape and wine industry with particular focus on the Mid-America region.

Community Service:

Dr. Suzy Cutbirth, Director of the Southwest Regional Professional Development Center.

Received \$450,000 from the Missouri Department of Elementary and Secondary Education to hire, house, and supervise six full-time employees to work with the RPDC staff and other state consultants and supervisors of instruction.

The objective is to improve the academic performance of students with disabilities and ensure regulatory compliance in districts and/or schools in Southwest Missouri through consultation, support, and the delivery of professional development initiatives as developed by the Division of Special Education.

"Until you can apply the information you have learned, then and only then will you be rewarded."

Andy Fuehl

PAGE 7

Office of Sponsored Research and Programs

901 S. National Avenue

Carrington Hall 422

Springfield, MO 65897

Phone: 417/836-5972

417/836-6888

Bill Alter, Director

Tracey Poston, Associate Director/Compliance Officer

Marina Zordell-Reed, ERA Coordinator

Bruce Richards, Research and Instructional Designer

Coordinator

Debi Bick, Proposal Development Specialist Janene Proctor, Administrative Secretary

Courtney Towe, Student Worker

Shannon Winstead, Part-time Employee

James P. Baker, VP for Research & Economic

Development, is the authorized institutional

representative to sign for proposals, grants and

contracts.

About OSRP

Our Mission: To increase the number and quality of grants awarded to faculty and staff by providing effective assistance.

OSRP provides assistance to all faculty and staff in developing and submitting competitive grant proposals, initiating new awards, and non-financial administration of grants and contracts.

OSRP assistance includes:

- Expanding your thinking about research and program development.
- Conducting grant writing workshops and online training.
- Registering you for SPIN and SMARTS—access to electronic funding sources.
- Coordinating proposal development teams.
- Assisting in developing project budgets.
- Reviewing and editing proposal drafts.
- Submitting proposals via hardcopy and electronic routes.

www.srp.missouristate.edu



http://www.The Compliance Corner

Compiled by Tracey Poston

Request for Comments on Categories of Research That May Be Reviewed By the Institutional Review Board (IRB) Through an Expedited Review Procedure:

The Office for Human Research Protections (OHRP) is requesting comments on a proposed amendment to item 5 of the categories of research that may be reviewed by the institutional review board (IRB) through an expedited review procedure, last published in the Federal Register on November 9, 1998 (63 FR 60364).

It has come to OHRP's attention that there has been confusion in the research community about expedited review category 5. OHRP is proposing to amend expedited review category 5 to clarify that the category includes research involving materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research.

Expedited review category 5 also includes research involving materials that will be collected solely for non-research purposes.

In addition, OHRP is requesting comments on the entire expedited review list that was last published in the Federal Register on November 9, 1998 (63 FR 60364) to determine if other changes are needed. OHRP is also specifically requesting comments on the Secretary's Advisory Committee on Human Research Protections recommendation to revise expedited review category 7.

As required under 21 CFR 56.110(a), FDA also will publish in the Federal Register a list of categories of research that may be reviewed by the IRB through an expedited review procedure. FDA intends to issue the list concurrently with OHRP's issuance of its final notice, and in compliance with 21 CFR 10.115 (good guidance practice regulations). This approach maintains FDA's practice of moving in tandem on this issue with OHRP.

Submit written or electronic comments on this notice by December 26, 2007. Written comments may be sent to EXPEDITED REVIEW, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments also may be sent via e-mail to expeditedreviewohrp@hhs.gov, or via facsimile at 301-402-2071. Comments received within the comment period, including any personal information provided, will be made available to the public upon request.

The notice can be accessed at: http:// www.hhs.gov/ohrp/ documents/20071026.htm.