



RESEARCH FORUM

Quarterly: Issue 35

Newsletter for The Office of Research Administration

Fall 2009

Building Research in Pillar Areas: Diabetes, Cardiovascular Diseases, Metabolic Disorders



**Research Administration
Has a new Website**

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[Research Administration Website](#)

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Why a Research Pillar?

Cardiovascular disease is the leading cause of death and disability in the US, while nearly 10% of the US population has been diagnosed with either type 1 or type 2 diabetes or other metabolic disorders. Because these chronic diseases are so pervasive in our society and also represent areas of significant research strength at Upstate, they were designated as one of Upstate's four disease-centric research pillars. A major research goal is to understand degenerative changes that occur in these chronic diseases in order to apply new findings to prevent and better treat them and ultimately contribute to the knowledge base that will lead to decreased morbidity and mortality.

Faculty from more than nine basic and clinical departments at Upstate are involved in diabetes-, cardiovascular disease-, and metabolic disorder-related research, stimulating cross-departmental collaborations and interdisciplinary research.

Current Funded Research

Professors Ruth Weinstock, MD/PhD, and Paula Trief, PhD, from the Departments of Medicine and Psychiatry, brought the first NIH-funded co-PI project to Upstate. Their five-year study, "Weight Loss in Primary Care: A Translation of the Diabetes Prevention Program," is adapting a successful weight loss intervention, for delivery through primary care practices. The

project will measure outcomes, such as weight loss, blood pressure, and psychosocial outcomes of health behaviors and health-related quality of life, as well as the cost-effectiveness of delivering the program in primary care settings. The significance of this study is replicability into primary care practices to reach large numbers of persons and assist them to successfully lose weight and maintain weight loss reversing the alarming rise in diabetes, cardiovascular complications and other obesity-related illnesses.

Dr. Trief has also received continuation funding for a second diabetes-related research project, "Improving Diabetes Outcomes: The Diabetes Support Project." This unique project tests whether an intervention that targets couples and their relationships leads to better and more lasting improvements in blood sugar control than one that focuses only on the individual. Success could lead to a tailoring of other interventions to include partners.

One of Upstate's Empire Scholars, George Holz, PhD, is currently conducting NIH-funded research projects that are taking a basic science approach to diabetes treatment. One of these studies, "Insulintropin: A Modulator of B-Cell Glucose Signaling," is looking to elucidate the complex signal transduction properties of glucagon-like peptide-1 (GLP-1) that explain its effectiveness as a blood glucose lowering agent when used to treat type 2 diabetes.

Most cardiovascular research at Upstate is being conducted by faculty in basic science departments, such as Cell and Developmental Biology. Co-PIs, Drs. Jean and Joseph Sanger, are funded by NIH to analyze mutation and/or deletion of specific proteins at the single-cell level. This research is designed to yield novel insights into myofibril assembly, maintenance and myopathies. Assistant Professor, Jeffrey Amack, PhD, was recently awarded funding from NIH to identify genes that may aid in diagnosis, treatment, or prevention of congenital heart disease in a zebra fish model. With an Intramural Equipment Grant and departmental funds, Upstate has created a zebra fish shared housing facility in the Department of Laboratory Animal Resources to support this and other zebra fish research.

Upstate faculty in other departments, such as Pharmacology and Biochemistry and Molecular Biology, are pursuing mechanistic research supported by NIH, the American Heart Association, The Georg Fund of the Central New York Community Foundation, and other sources at this time.

The Future

By bringing Upstate faculty from different departments and disciplines together under the Diabetes, Metabolic Disorders and Cardiovascular Diseases pillar, collaborative, multi- and inter-disciplinary basic, clinical, and translational research will grow significantly in the coming years.



*Comments from the Vice President for Research
Steven R. Goodman, Ph.D.
5 and 10*

President David Smith has challenged the Upstate Medical University Research Community to increase research expenditures, in his 5 and 10 plan, by 10% annually. Can we do it? I firmly believe that we can.

Why do I think that we can accomplish this when extramural funding beyond ARRA remains bleak? There are a number of reasons that we can be successful in reaching this goal:

1. Increases in research expenditures lag many months behind getting a new grant or recruiting a funded investigator and we have done very well in both areas over the last year. Let's look at some of the successes in this area:
 - A. We recruited outstanding funded investigators like our two newest Empire Scholars, Bill Kerr and Francesca Pignoni, and our new Chair of Pharmacology, Ziwei Huang, and several other well funded investigators.
 - B. We have successfully competed for \$3.4 million of ARRA funding.
 - C. We have been very successful in bringing in large grant awards from the State such as the money for the SCID mouse facility; and from NIH, such as the new Center grant awarded to members of our Neuroscience department, as well as many new RO1 and other awards.
 - D. We have made a great effort to increase our visibility and interactions with regional bio-industry. The goal is to increase our Industry sponsored research and this goal is beginning to be realized.
2. We formed a wonderful Research and Graduate Education Leadership Team (ReGELT). With Jeremy Shefner focused on increasing clinical and translational research, Nancy Nussmeier making our compliance issues easier to deal with for Upstate faculty and regional industry, and Steve Youngentob improving the education and quality of life of pre-doctoral and post-doctoral trainees, we are together creating an environment conducive to reaching our research goals for many years to come.
3. We have a detailed and well thought out blueprint for success in the "Strategic Plan for Strengthening Research." We just need to follow the blueprint.
4. Most importantly we have a great research faculty that has my respect and admiration. Our success in reaching these lofty goals will be based on the hard work and brilliance of this group.

Can we reach the 10% increase in research expenditures? We can and we will, **together**.



For November.....

What Research Administration Can Do For YOU!

Target audience: Faculty Conducting Research and their Support Staff, especially Faculty new to Upstate.

November 19, 2009 9 – 10 AM. Rm 3507, Setnor

Coming in December.....

Core Research Facilities

ReGELT:***New Upstate Research Leadership Team Charged with Bringing in the Gelt***

With the acceptance of research and graduate education leadership positions, Jeremy Shefner, MD/PhD; Nancy Nussmeier, MD; and Steve Youngentob, PhD, join Steve Goodman, PhD, Vice President for Research, as members of ReGELT—the Research and Graduate Education Leadership Team. This team is charged with growing our research enterprise—bringing research “gelt” to Upstate.

Dr. Youngentob accepted the position of Associate Dean for the College of Graduate Studies in October, 2008, and has worked since that time to strengthen all aspects of the graduate program, including recruitment, admissions, curriculum, and tracking graduates. Dr. Youngentob worked with Dr. Goodman, Dean of the College of Graduate Studies, to develop the first COGS Curriculum retreat and important steps to reinvent the first year curriculum.

Dr. Jeremy Shefner continues as Chair of the Department of Neurology and in addition, recently accepted the position of Associate Vice President for Clinical and Translational Research. In this new role, Dr. Shefner will develop a Clinical Research Office; oversee, develop and grow the Center for Clinical and Translational Research (CCTR); oversee the Clinical Research Unit; and serve as Upstate’s representative in the SUNY Academic Health Centers Collaboration in Clinical and Translational Research. To grow clinical and translational research at Upstate, Dr. Shefner will oversee the establishment of clinical databases to support clinical research, the development of a biobank, and the creation and oversight of a mechanism for research tracks for residency and fellowship programs.

In her new role as Associate Vice President for Research Integrity, Dr. Nussmeier, who will also retain her position as Chair of the Department of Anesthesiology, will oversee the IRB, CHUA, and Quality Assessment and Improvement Program (QAIP). She will serve as Upstate’s Research Conflict of Interest Chair and Research Integrity Officer on new cases.

Along with Dr. Goodman, these Upstate faculty—Drs. Youngentob, Shefner, and Nussmeier—comprise the ReGELT. Through their leadership, we look forward to an exciting time of growth in research at Upstate.

Ask ReGelt?

[Tell Me More about Research and Graduate Education at Upstate.](#)

Want more information about research and graduate education at Upstate? Just ask ReGELT. Members of this leadership team will answer your inquiries. Submit questions to Barbara Humphrey at humphreb@upstate.edu. Questions and responses will be posted on the Research Administration web site and summarized in future issues of Research Forum.

SUNY REACH...***Making an Invest in Research to Serve the Health Needs of New Yorkers***

SUNY’s Academic Health Centers (AHC), Buffalo, Downstate, Stony Brook, Upstate, and the College of Optometry, have a unique public mission—to serve the health care needs of New Yorkers by educating healthcare professionals, providing clinical care, and supporting biomedical research dedicated to improving human health. These AHCs are now united in their quest to pursue a biomedical research plan that addresses the state’s most serious health care concerns through SUNY REACH.

With initial capital from the five partners and the Research Foundation of SUNY, this new collective is ready to implement Phase I of their research plan. With the establishment of four disease-centric research pillars representing the leading causes of morbidity, mortality and rising health care costs in the state—Cancer, Infectious Diseases and Emerging Pathogens, Disorders of the Nervous System, and Diabetes and Cardiovascular Disease—SUNY REACH has allocated its initial funds to grow research in three areas: Neuroscience and Vision Research, which both fall under the Disorders of the Nervous System pillar, and Clinical and Translational Research, which is a major component of all pillars. Funds will be used to support meetings and symposia, pilot research projects, web site development, videoconferencing equipment, and administrative and IT support to jump start and sustain faculty collaborations.

Neuroscience funding will focus on three areas: 1) SUNY Institute on the Neuroscience of Substance Abuse (SINSA), which is being formed to study addiction, mental illness, and other disorders that can result from the abuse of alcohol and other addictive substances; 2) Neurodegenerative Diseases and Stem Cell Therapeutics, focusing on causes and treatments for Alzheimer’s Disease, Parkinson’s Disease, Multiple Sclerosis, and Amyotrophic Lateral Sclerosis; and 3) Receptors and Brain Disease, to focus on acute brain injuries characterized by altered receptor function, such as stroke, epilepsy, and ischemic and traumatic brain injury. Funds to support Vision Research will expand the SUNY Eye Institute and focus on research and training in the major blinding diseases, such as age-related macular degeneration, glaucoma, cataracts, and diabetic retinopathy, retinitis pigmentosa, myopia, and amblyopia.

In the area of Clinical and Translational Research, funds will be used to create a SUNY Clinical Research Organization. This entity will offer one-stop shopping for industry and clinical scientists wanting to conduct clinical trials at multiple SUNY sites and establish the institutional size and structure needed to successfully vie for large extramural awards, such as NIH Clinical Translational Science Awards.



NIH Public Access Policy: PI's, what you don't know will hurt you!

What is the NIH Public Access Policy?

All PIs with authorship of peer-reviewed publications accepted for publication on or after April 7, 2008 that arise from direct NIH funding via grant, cooperative agreement or contract must comply with the NIH Public Access Policy or face the consequences, which could include NIH funding delays or denials. This policy grew out of a 2005 Congressional mandate that the public have access to biomedical and life sciences research funded with their tax dollars, and implements Division G, Title II, Section 218 of PL 110-161, the 2008 Consolidated Appropriations Act.

Why Public Access?

The NIH Public Access Policy ensures that the public has access to the published results of NIH research in order to advance science and improve human health. Public access is not open access. Open access is free and unrestricted use of published materials; public access provides free use within 12 months of publication, but use of that material is subject to the copyright and/or related license terms of the respective authors or publishers.

How Do PIs Comply with the NIH Public Access Policy?

PIs are responsible for compliance with this policy by directly submitting or assuring submission of applicable manuscripts in PubMed Central (PMC), the NIH free digital archive of biomedical and life sciences journal literature. Before signing a publication agreement or similar copyright transfer agreement, PIs must make sure that the agreement permits submission to PMC in accordance with the NIH Public Access Policy.

Four submission methods assure that applicable papers are submitted to PMC and PIs are in compliance with the NIH Public Access Policy:

1. publish in a journal that deposits final published articles in PMC without author involvement. A list of these journals is found at http://publicaccess.nih.gov/submit_process_journals.htm.
2. request a publisher deposit a specific article in PMC.
3. deposit the final peer-reviewed manuscript in PMC via the NIH Manuscript Submission (NIHMS) at <http://www.nihms.nih.gov/>.
4. complete submission of final peer-reviewed manuscript deposited by a publisher in NIHMS.

How is Compliance with the NIH Public Access Policy Documented?

Beginning on March 25, 2008, anyone submitting an application, proposal or report to the NIH must include the PMC reference number (PMCID) when citing applicable papers that they author or that arise from their NIH-funded research. If the PMCID is not available because the paper has not yet been published or was published less than three months prior to the submission, an NIH Manuscript Submission number (NIHMSID) may be used. If the Journal submits directly to PMC on behalf of the authors, the statement "PMC Journal – In Process" may be used in lieu of a PMCID.

PIs should add the PMCID or the acceptable alternatives mentioned above in their Biographical Sketches and update their biosketches to replace NIHMSID and "PMC Journal – In Process" when PMCIDs become available. Applicants should include PMCIDs or alternatives in the "Bibliography & References Cited" section of the SF 424 R&R, PHS 398 or PHS 416-1. PMCIDs (or alternatives) should be included in the "Publications List" of Competitive Renewal applications, the Publication section of Noncompeting Continuation Progress Reports, and in the list of publications resulting from the project in Final Progress Reports.

How is Compliance with the NIH Public Access Policy Monitored?

Compliance with the NIH Public Access Policy is a statutory requirement and a Term and Condition of a grant award or Cooperative Agreement. NIH Program Officials will review submissions for compliance and notify PIs via email, with a copy to the Sponsored Programs Office, that note specific citations of papers included in proposals, applications or progress reports that appear to fall under the policy but lack demonstration of compliance (PMCID, NIHMSID or reference to a Journal submission). PIs will have the opportunity to respond that the paper is in compliance by citing the PMCID or alternatives or explaining why the paper is not covered by the policy.

Continued on the next page



What you don't know will hurt you! Continued from pg 4.

NIH is currently in an "educational mode," but there is no telling when the "education mode" will be replaced with a more punitive response. Failure of PIs to provide evidence of compliance with the NIH Public Access Policy is a violation of the terms and conditions of an NIH award and may result in suspension of awards found to be out of compliance, pending correction action, or termination of the award for cause.

What Resources are Available to PIs to Assure Compliance with the NIH Public Access Policy?

The NIH public access web site (<http://publicaccess.nih.gov/index.htm>) provides detailed information for PIs on determination of applicability and how to comply, including two PowerPoint presentations, a brochure, and other print and electronic media materials.

Help is also available right here at Upstate Medical University. The Office of Sponsored Programs is taking the following steps to educate PIs of the policy, remind them of the need to comply, and assist them to determine which publications are applicable to the policy. Visit their web site at http://www.upstate.edu/researchadmin/sponsored_programs/ or contact Jennifer Rudes (rudesj@upstate.edu), Dave Temple (templed@upstate.edu) or Gerri Paparella (paparelg@upstate.edu) for assistance.

The Health Sciences Library Reference Staff provides access to PubMed Central (<http://www.pubmedcentral.nih.gov/libproxy2.upstate.edu/>) and assists PIs to obtain and/or identify PMCIDs for their applicable publications.

The Sponsored Programs Office and HSC Library sponsored an NIH Public Access Policy Seminar on September 9, 2009, that included a videocast PowerPoint presentation and with David Gillikin, Chief, Bibliographic Services Division at NLM, as well as with SPO's Jennifer Rudes and HSC Library's Brad Long. A video of these seminar, as well as copies of the two PowerPoint presentations will be available on the HSC Library website shortly.

New and Shorter NIH Application

Competing [new, renewal & revised] applications submitted for deadlines on/after 01/25/2010 require use of new SF-424 and PHS-398 forms and instructions, which should be available by December.

The goal of the revision was to align the application structure and content with the "enhanced" review criteria and to shorten its length. Changes are being made to the Research Plan, Resources, and Biographical Sketch.

Basically, the new "Research Strategy" section and been restructured and limited to 12 pages for R01's and other Funding Opportunities [FO's] previously allowing 25. Those FO's that previously allowed less than 25 [R03's & R21's] will change to 6 pages. Specific instructions will be provided for all others.

The Facilities and Other Resources will require a description of how the scientific environment will contribute to the probability of project success, unique environmental features, and for Early Stage Investigators, the institutional investment in the PI, including resources, classes, etc.

A Personal Statement must be included in the new Biographical Sketch, replacing the former Positions and Honors, Peer-reviewed Publications and Research Support. Publications are restricted to 15 and should be chosen based upon recency, importance to the field and relevance to the project.

For more details, see NIH Notice NOT-OD-09-149 at:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-149.html>



SPO Needs Help --- yours!

With a 53% increase in proposals for extramural funding in the previous fiscal year, and no increase in staffing; the “Pre-award” Sponsored Programs Office requires assistance from our Investigators and staff.

Investigators/staff should involve the SPO immediately upon deciding to submit a response to a specific funding opportunity. In this way, the SPO can assist in the non-technical proposal development, suggest an internal target date based upon anticipated volume for that deadline and accomplish submission on a timely basis. While the Investigator is developing/refining the technical component; the administrative, fiscal and compliance elements may be previewed by the SPO well in advance of the deadline.

Once previewed, assembled and transmitted to the SPO by the target date, final review and submission can be easily accomplished.

Due to deadline crunches and the requirement for administrative review and sign-off, many institutions have initiated rigid internal deadlines well in advance of sponsor receipt dates. At those sites, proposals not received by that date are not submitted. Period!

In an effort to encourage and expedite the submission of successful proposals, Upstate’s SPO has resisted adopting that posture. With the increased activity, however, the SPO needs Investigator/staff cooperation if proposals are to continue to be submitted on a timely basis.

Non-technical proposal and submission questions may be directed to SPO contacts David Temple, Jennifer Rudes and Gerri Paparella at 464-5476.

The SPO exists to serve Upstate’s Investigators. It needs Investigator/staff cooperation in order to do it well, however. Help the SPO to help you.

Upstate’s Indirect Cost Rates

Upstate’s current federally-negotiated Facilities & Administrative [F&A] Rate is 58%. It will be 59.5% effective 07/01/2011. All proposals submitted to federal agencies must include these rates.

Submissions to non-federal sponsors should include the maximum Indirect Cost, Administrative Overhead, or F&A rate allowed by written sponsor policy. Investigators should obtain that rate from the application instructions or by contacting the sponsor prior to budget preparation.

The institution will continue to support corporate-sponsored research activities at the 25% level.

In the absence of sponsor policy, please consult with the Pre-award Sponsored Programs Office staff at:

<http://www.upstate.edu/researchadmin/directory.php>:

All proposal budgets must provide for full F&A Cost recovery. Due to fiscal constraints, Upstate cannot “waive” or reduce any of these rates upon application submission.

IRB Update:

Change in Policy for Reporting Unanticipated Problems:

We have significantly updated the policy for reporting unanticipated problems, involving risks to subjects or others (including adverse events) and protocol deviations. These changes have been made to comply with OHRP and FDA guidance. The changes affect both what is required to be reported to the Upstate IRB and the reporting process.

The purpose of the revised policy is to ensure the prompt reporting of unanticipated problems to the IRB, so that human subjects can be better protected from avoidable harms.

It is expected that reports of unanticipated problems may warrant consideration of substantive changes in the research protocol or informed consent process or document.

Unanticipated Problems: includes any incident, experience, or outcome that meets all of the following criteria:

A. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

B. related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research);

and

C. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

An adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Includes both physical & psychological harms.

It should be noted that only a small subset of adverse events occurring in research subjects are unanticipated problems that must be reported to the IRB.

In general the Upstate IRB will now only accept reports of individual adverse events if these events meet the three criteria of an unanticipated problem, as described above.

In order to ensure that appropriate steps are taken in a timely manner to protect other subjects from avoidable harm, the IRB expects investigators to promptly report Unanticipated Problems to the IRB, as follows:

1. Unanticipated Problems that are serious adverse events should be reported to the IRB within 1 week of the investigator becoming aware of the event.
2. Any other Unanticipated Problem should be reported to the IRB within 2 weeks of the investigator becoming aware of the problem.

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We have posted several items on the IRB website to assist researchers with this policy:

1. A step by step Algorithm for Determining Whether an Adverse Event is an Unanticipated Problem: http://www.upstate.edu/researchadmin/document/up_ae_flowchart.pdf
2. "To whom it may concern" letter, to assist communication of this policy (effective 9/1/09) with research sponsors <http://www.upstate.edu/researchadmin/compliance/irb>
3. Unanticipated Problems & Adverse Event Report Form – provides the criteria to assess whether reporting is required and includes relevant definitions http://www.upstate.edu/researchadmin/document/up_ae_form.doc

For additional guidance and a detailed explanation of reporting requirements, please review the entire policy at: http://www.upstate.edu/researchadmin/document/adverse_event_guidelines.pdf

Change in Policy for Reporting Protocol Deviations:

There is no regulatory requirement to report protocol deviations to the IRB (unless they represent unanticipated problems) and most protocol deviations will not warrant consideration of substantive changes in the research protocol or informed consent process or document. Therefore, only Protocol Deviations that meet the definition of an unanticipated problem should be submitted to the IRB.

If a protocol deviation meets the above definition then it must be reported to the IRB promptly using the Report of Unanticipated Problems & Adverse Events.

The above policies were presented to research staff at the September 2nd 'Hot Topics in Research' presentation; however, we are aware that additional presentations or small group education sessions may be needed. Please let the IRB office know if you would like to attend a session.

Upstate IRB Completes New Registration Requirements

In response to a 1998 report from the Office of the Inspector General on the challenges facing Institutional Review Boards (IRB's), the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA) have created an updated and streamlined IRB registration process. The new registration law went into effect on July 14, 2009 with a two-month grace period for previously registered IRB's.

The new registration will collect more detailed information about IRB's (for example, the number and types of studies reviewed), which will help the FDA and OHRP, provide site-specific information and to assist in identifying sites for inspection.

On July 28, 2009 the SUNY Upstate Medical University Institutional Review board received confirmation for its updated registration and is now in full compliance with the new federal regulations regarding the registration of Institutional Review Boards. The FWA, IORG, and IRB registration numbers have not changed, however the expiration date of the IRB registration has been updated.

The current registration numbers and expiration dates can be found on the IRB website in the 'Information Packet for Study Sponsors.' Please note: the information packet can only be accessed from computers on the Upstate campus.

IRB Meeting Dates and Deadlines can be found on our website at:

<http://www.upstate.edu/researchadmin/compliance/irb/deadlines.php>

IBC Meeting Dates and Deadlines can be found on our website at:

http://www.upstate.edu/researchadmin/document/ibc_meeting_dates.pdf

Institutional BioSafety Committee (IBC)

Information from the CDC regarding exposure to vaccinia virus:

(The guidance documents referenced below are posted on the IBC web site)

Every year the Centers for Disease Control and Prevention (CDC) receives reports concerning laboratory workers who have had inadvertent exposure to vaccinia virus. Many of these exposures result in infections. Adverse events stemming from vaccinia virus infections are possible, including transmission of the virus from infected lab workers to other persons.

The enclosed information is intended to highlight the following key points:

1. The Advisory Committee for Immunization Practices (ACIP) recommends smallpox vaccination as preventive measure against inadvertent infection and adverse events for researchers who manipulate non-highly attenuated vaccinia virus.
2. Laboratory directors and workers need to understand the benefits of vaccination as well as the potential risks.
3. Inadvertent vaccinia virus infections constitute a public health concern due to the possibility that the virus can be transmitted to an individual's personal contacts, and to health care workers.
4. Screening for contraindications to smallpox vaccine is important because severe complications can occur in persons with underlying risk factors (e.g., pregnancy, immunodeficiencies, or dermatologic conditions such as eczema). Those with contraindications to smallpox vaccine may wish to seek counseling about the pros and cons of working with live vaccinia virus.

To aid you in providing appropriate guidance for laboratory workers at your institution, we have enclosed the following documents:

1. CDC. Smallpox vaccine: recommendations of the Public Health Service Immunization Practices Advisory Committee. *MMWR* 1978;27:156–8, 163–4.
2. CDC's report summarizing recent vaccinia virus infections in laboratory workers *Laboratory-acquired vaccinia exposures and infections--United States, 2005-2007*. *MMWR Morb Mortal Wkly Rep*, 2008. **57**(15): p. 401-4.
3. Review of recent vaccinia virus infections in laboratory workers: MacNeil, A.,M.G. Reynolds, and I.K. Damon, *Risks associated with vaccinia virus in the laboratory*. *Virology*, 2009. **385**(1): p. 1-4.
4. Biosafety guidelines for laboratories utilizing vaccinia virus found in: US Department of Health and Human Services, CDC, National Institutes of Health.

For any questions or concerns please contact the Poxvirus program: Poxvirus Program Hotline 404-639-4129, or

CDC-Info800-CDC-INFO (800-232-4636); cdcinfo@cdc.gov

American Recovery & Reinvestment Act (ARRA) Awards for Upstate

The recent ARRA legislation provides an unprecedented level of funding (\$8.2 billion in extramural funding) to the NIH to help stimulate the US economy through the support and advancement of scientific research.

Since September 30, 2009, Upstate has received 10 "Notices of Award" from the NIH resulting from ARRA money. Research Administration would like to highlight one of our recent ARRA awards received by Dr. Christopher Turner, Department of Cell & Developmental Biology.

The Turner lab is studying the signaling mechanisms that control cell migration during cancer cell invasion and metastasis. This NIH ARRA supplement for his R01 grant of 18 years will provide funds for the purchase of a fully integrated and automated live cell microscope/imaging system. This state-of-the-art system, which replaces aging existing equipment, will permit the simultaneous tracking and detailed motility analysis of multiple cells or samples. As a result, experiments that used to take a week or more to complete can now be accomplished within hours.

For Upstate researchers whose ARRA Challenge grant requests were not funded, NIH recommends converting your applications to R01 or R21 applications and submitting them as new applications for an upcoming deadline. The next R01 deadline is February 5, 2010, and the next R21 deadline is February 16, 2010.

Research Administration Adds Proposal Development to its Continuum of Services to Researchers

The Research Administration Office is proud to announce that it is now able to offer proposal development services, including limited grant writing and editing assistance to researchers preparing extramural grant applications for submission. These services will include one or more of the following, and will be offered on a first come, first served basis:

- Review of funding opportunity announcements to assist researchers to determine their eligibility to apply and to frame a proposal that best meets the sponsor's funding intentions
- Prepare non-scientific, non-technical narrative components of the proposal
- Edit scientific and technical components of the proposal for language, grammar, and adherence to formatting requirements of the sponsor
- Refer to Sponsored Programs Office for assistance with administration, budgetary and compliance components of the proposal

Researchers seeking proposal development assistance should contact Barbara Humphrey at 464-4322 or humphreb@upstate.edu as early in the process as possible.

Quality Assessment and Improvement Program (QAIP)

Frequently Asked Questions (FAQs):

Question: *How long does an investigator/study site have to keep old study records?*

Answer: There are several layers of regulations, policies and guidelines to consider.

The first thing you have to do is to figure out who has jurisdiction over your study and what regulations apply (the FDA, the Department of Health and Human Services, study sponsor, or all). You will also need to consider the Good Clinical Practice Guidelines and lastly the Upstate IRB Guidelines and Policies (which include HIPAA).

FDA regulations:

Investigational New Drug Application (IND):

21 CFR 312.62 (c) Record retention. "...2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified".

Investigational Device Exemption (IDE):

21 CFR 812.140 (6) (d) Retention period. "...2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol".

Department of Health and Human Services Regulations:

45 CFR 46.115(b): "The records...shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research".

ICH Good Clinical Practice Guidelines:

4.9.5: "Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product.. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained".

Upstate IRB Guidelines and Policies:

"Retaining Informed Consent Documents (pg 44-45):

For Studies not subject to the HIPAA Privacy Rule (no authorization included in consent document): Documentation of the informed consent of the subjects - either the signed informed consent form or the short form and the written research summary - are records related to conducted research that are typically held by the PI and must be retained for at least three years after completion of the research, unless the IRB waived the requirement for informed consent or the requirement for documentation of informed consent (45 CFR 46.117). In addition, other regulations may apply and require retention of these records for a longer period of time.

For Studies that are subject to the HIPAA Privacy Rule (authorization is included in consent document):

Documentation of the informed consent and authorization to use and share personal health information of the subjects - the signed informed consent and authorization form - are records related to conducted research that are typically held by the PI and must be retained for at least six years from the date signed by the subject (or subject's representative) or from the date when last in effect, whichever is later.

Because there may be no specific expiration date on the consent/authorization form, the current guidance is that the consent/authorization form should be kept indefinitely. Such records may be preserved in hardcopy, electronic or other media form and must be accessible for inspection and copying by authorized representatives of the institution and federal agencies at reasonable times and in a reasonable manner.

If the PI leaves Upstate, arrangements must be made to leave the consent/authorization forms with the Department. These arrangements should be communicated to the IRB office".

The Bottom Line:

For study records other than the signed consent/authorization forms (which should be kept indefinitely), once the minimum time required by the applicable regulations has passed, it is up to the sponsor. It is expected that the investigator will retain all study records until notified by the sponsor that they may be disposed of. Record retention requirements should be specified in the protocol/contract. Do not destroy any study records without first checking with the sponsor.

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*Thanks to the above Upstate Medical University staff for their contribution to this issue of the Research Forum.

If you would like to contribute to this Newsletter please contact [Barbara Humphrey](#).

If you would like to not receive this newsletter or you know of someone who should receive this newsletter please contact [Kathleen Pazaras](#).

IIBMST...

Facilitating Collaborations around the World

When the presidents of Upstate Medical University, the Technion Israel Institute of Technology, and the National Cheng Kung University signed the International Institute of Biomedical Sciences and Technology (IIBMST) Memorandum of Understanding in September, 2009, they opened the door for sustainable, global collaborations between faculty of these three institutions. Upstate's VP for Research, Steven Goodman, PhD, who serves as the institute's executive director, described the importance of this collaboration, "We are breaking down the barriers between scientific disciplines and nations to bring together great minds around the globe to solve health problems that require teams of researchers to solve."

While areas highlighted for research collaboration are still being discussed and will be made by faculty of the three institutions, Dr. Goodman expects that they will include Upstate's four research pillars—cancer; infectious diseases; diabetes, metabolic disorders and cardiovascular disease; and disorders of the nervous system.

Procedures are being finalized to enable researchers at Upstate, the Technion and NCKU to register and become part of this new, inter-continental collaborative. They will be posted on [Upstate's IIBMST](#) and reported, along with successful collaborations, in future issues of ***Research Forum***.

LUNGevity

Foundation Partnership Increases Funding for Lung Cancer Research at Upstate Medical University

With grant funds from the LUNGevity Foundation, the Connolly Endowment for Lung Cancer Research and the Hendricks Fund, Associate Professor of Pharmacology, Jing An, MD/PhD, will develop new radio sensitizers as potential therapeutics for lung cancer treatment. The LUNGevity Foundation funds have been granted as a match to the funds committed from the Connolly Endowment and Hendricks Fund. These funds represent the first investment in lung cancer research at Upstate by the LUNGevity Foundation. LUNGevity was first invited to consider supporting lung cancer research by the Upstate Foundation, based upon their efforts to raise money for lung cancer through various events, such as the annual Cancer Walk, Run & Rally held this year on September 20, 2009. At this event, LUNGevity Foundation representatives officially presented their research grant to Upstate, joined by Leslie Kohman, MD, who committed the Connolly Endowment Fund match. This funded research will be conducted by Dr. An, who came to Upstate this fall from the Burnham Institute for Medical Research in La Jolla, California, joining research partner Ziwei Huang, PhD, recently appointed Chair of the Department of Pharmacology.

Following an intramural Request for Proposals and joint review of submissions by Upstate's Research Advisory Committee and representatives of the LUNGevity Foundation, Dr. An's proposal was selected for funding because it addresses a significant need for satisfactory lung cancer treatments. Current treatment regimens administered to lung cancer patients typically result in severe cytotoxicity and damage to non-cancer cells. Dr. An's approach to treat lung cancer by developing specific inhibitors of molecular pathways that control tumor cell growth offers a promising treatment alternative and builds upon her previous research accomplishments. Her proposal, "Development of New Radio sensitizers for Human Lung Cancers," was recommended for funding by both the Research Advisory Committee and LUNGevity Foundation. This research is key in the development of new, targeted drugs that facilitate the use of radio- and/or chemotherapy at lower doses with higher efficacies. It also represents an important step in advancing promising lead compounds for preclinical research and, eventually, clinical trials.