Research Meeting 1/18/18: Agenda

• Announcements and Updates – Dave Mankoff
• Finance and Administration Update – Bill D’Arcy
• Grant components update – Bev Collins
• Topical Presentation: - Bob Mach – Research Update: PET Radiochemistry Program
New and Announcements
David Mankoff
Research Division Meeting Schedule
2017-2018

• 7/13/17  No meeting – Happy Summer!
• 8/17/17  Topical Presentation: Tessa Cook (Informatics)
• 9/21/17  Research Executive Committee
• 10/5/17* Topical Presentation: Ravi Reddy (Quant Imaging)
• 11/16/17 Topical Presentation: Tim Roberts (CHOP)
• 12/14/17* Research Executive Committee (1:00-2:00)*
• 1/18/18** Topical Presentation: Jim Delikatny (Mol Imaging) (1-2PM)
• 2/15/18  Topical Presentation: Bob Mach (Mol Imaging)
• 3/14/18* Research Executive Committee
• 4/12/18* Topical Presentation: Mike Soulen (Clinical Res) (1 – 2PM)**
• 5/17/18  TBD
• 6/14/18* Research Executive

*Note date change
**Note Time change
Research Division Grand Rounds Speakers 2017-2018

• 9/12/17 Brandon Fornwalt
• 10/10/17 Zhi-Pei Liang
• 10/17/17 Claudine Gauthier
• 11/14/17 RSNA Resident Presentations
• 12/12/17 Mark Sellmyer
• 3/6/18 TBD
• 3/20/18 TBD
• 5/22/18 Hugo Aerts

(note 2/20/18 change)

• Also:

— Pendergrass Symposium Friday, 6/22/18
New ARR NIF Funding Rankings!

NIH Awards to Medical School Departments Diagnostic Radiology in Fiscal Year 2017

The total amount of NIH dollars going to Contact PIs having primary appointments in Diagnostic Radiology Departments has increased 17.40% in FY 2017 as compared to FY 2016 ($500,850,376 vs $426,629,827). The Academy would like to thank Stanley Baum, M.D., for his annual efforts to compile the appropriate data and provide us with such valuable information.

<table>
<thead>
<tr>
<th>No.</th>
<th>Institute</th>
<th>Award Amount</th>
</tr>
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<tr>
<td>1</td>
<td>Massachusetts General Hospital</td>
<td>$66,861,100</td>
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<tr>
<td>2</td>
<td>Univ Of Pennsylvania Sch Of Medicine</td>
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<td>7</td>
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<td>8</td>
<td>Mayo Clinic</td>
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<td>Yale University Sch Of Medicine</td>
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<td>Brigham and Women's Hospital</td>
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<tr>
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<td>University Of Michigan Medical School</td>
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<td>12</td>
<td>University Of Minnesota Medical School</td>
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<td>New York University Sch Of Medicine</td>
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<td>University Of Washington Sch Of Medicine</td>
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<tr>
<td>17</td>
<td>Columbia Univ Of Physicians &amp; Surgeons</td>
<td>$9,294,916</td>
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</table>
Local and Other News

• Successful TBIC/ITMAT submission and review
  – 10/45 proposal funded
  – Thank to all reviewers who helped!

• Pendergrass Symposium abstract submission will open soon

• Radiology Presentation at Dean’s meeting of Chairs and Center Directors (SDSC) – Bob Mach on Radiochemistry

• S10 PAR’s are out again – May deadline, Mar internal letter of intent
Graduate Student Representation

• Penn graduate students considering representation by American Federation of Teachers (AFT).
  – Largely led by non-science graduate students
  – Vote planned in the next 1-3 months

• Information about the process and proposed representation is in mail from Beth Winklestein (Vice-Provost for Education) on 2/12/18
Administration/Finance Update
Bill D’Arcy
Radiology Financial Update

• Awards Received thru Jan. 2018
  – Received ~ $17.13 million – 21.9% increase from FY 17.

  Extramural funding expenditures thru Jan. 2018
  – Extramural funding expenditures at $18.75 million.
  – Exceeding last fiscal year’s record pace by 6% ($1,072,797).

  Proposals submitted thru Jan. 2018
  – Above last year’s pace by 20%.
Radiology Awards

- Radiology Awards Officially Received This Period:
  - David Cormode/ Polyarum Sub (R41)
  - Paul Yushkevich/ Northern California Institute for Research and Education Sub
Administrative Updates

– HIPAA certification
  • Mandatory certification.
  • Time period is now ANNUAL.
  • Can be found in knowledge link.

– February 5 Submissions
  • 10 - R01 Submissions - Thank You!!

– Dean’s Budget FY 19
  • Will be reaching out for any new awards to be received.
  • Thank you so far for the quick responses and cooperation.

– Effort Reporting
  • Scheduled to start February 2018.
  • Delays Currently in the Software Program
Administrative Updates

– Penn Profile/Online Directory
  • Please double check that correct phone number and address are listed.
  • This update drives many of Penn’s online profiles in Penn ERA, CAMS, etc.

– Report Updates
  • Should be receiving January updates this month
Grant Components Update
Bev Collins
How to Comply with NIH’s Public-Access Policy: Publications and Data
NIH Public-Access Policy: Make publications freely available

- All investigators funded by the NIH must submit to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication.
NIH Public-Access Policy

• Need PubMedCentral ID (PMCID) within 3 months
• Most journals will submit your manuscript for you. Some will wait 12 months.

• It can be archived in PMC, with a PMCID#, until it is made available to the public at the 12-month mark.
NIH Public-Access Policy

1. Make sure all publications resulting from NIH funding are deposited into PubMed Central
2. Make sure the publications are associated with your funding ID
3. Make sure you list these in MyBibliography
MyBibliography in MyNCBI

  - Good place to manage all your publications
  - Links to your NIH Commons account
  - Use for NIH progress reporting
  - Put the link into your biosketch as “Complete list of My Publications”
An objective analysis of process errors in trauma resuscitations.


PMID: 11073483

Nuclear structure of light thallium isotopes as deduced from laser spectroscopy on a fast atom beam.


PMID: 9954381

Role of deformation in the intrusion of the h9/2 levels below the Z=82 proton shell.


PMID: 10032097
Search results

Items: 5

1. An objective analysis of process errors in trauma resuscitations.

2. Nuclear structure of light thallium isotopes as deduced from laser spectroscopy on a fast atom beam.

3. Role of deformation in the intrusion of the h9/2 levels below the Z=82 proton shell.

Choose Destination
- File
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- Collections
- E-mail
- Order
- Citation manager
- My Bibliography

Add to My Bibliography

Recent Activity
- spejewski (5)
- Use of Radiology Procedure Codes for Patient Care: The Need for Standardization (1)
Journal Articles


   NIH Public Access Compliance: Complete. PMCID: PMC5548452
   Funding: No funding has been associated with this citation. Add award


   NIH Public Access Compliance: Not applicable Edit Status
   Funding: No funding has been associated with this citation. Add award
NIH Public-Access Policy:
Data Safety and Availability

• Data Management Plan (DMP)
• Data Sharing Plan
• Data Safety and Monitoring Plan (clinical trials)
What is a DMP?

- 2-page document
- Describes:
  - What data will be produced
  - How the data will be managed during the project
  - How the data will be handled after the project
  - How the data will be shared
DMP FYI

- DMP expectations are tightening over time
- Poor data management plans can make the difference in getting funding!
Data/Resource Sharing

- All grants seeking “$500K or more in direct costs in any one year” should explain how the final research data will be shared, or justifying why it cannot be shared,
- Applications that involve developing model organisms are to include plans for sharing and distributing these resources, and
- Studies involving large-scale human and non-human genomic data must adhere to the NIH Genomic Data Sharing Policy.
Sharing Venues

• By request
• On researcher’s personal website
• In the institutional repository  
  Preferred
• In a data repository
Data Planning and Management

The library will help you understand your research materials, plan for projects, and save and archive your work.

Build a Data Management Plan

- Learn about the DMPTool and other Data Management Plan basics

Manage Personal Research Materials

- Take a look at this guide from Purdue University about Personal Information Management (PIM)

Store and Back up Data and Files

- Find out about some storage and backup options for your digital files

You can also search Research DataQ for answers

Ask a data question

http://guides.library.upenn.edu/data-management
Looking for a repository where you can store your research data? The following directories may be helpful:

- Databib.org
- Re3Data.org (Registry of Research Data Repositories)
- NIH Data Sharing Repositories
- OpenDOAR

Primary Data Repositories

The following data repositories are frequently used by members of the Penn community for storing research data. Some are general repositories and repository services; others store specific types of data. If you have a suggestion for another repository to add to this list, please contact us!

- Figshare - cloud-based repository for all types of data
- Dryad Digital Repository - non-profit STM repository

ScholarlyCommons is the institutional repository that captures the research output of the Penn community and shares these outputs. The ScholarlyCommons Guide or email repository@upenn.edu for more information.

Data management for this project will be supported by the University of Pennsylvania. ScholarlyCommons will host, share, and disseminate the scholarly output. A multi-tiered disaster recovery plan for all of its content will ensure discoverability of content and ongoing support. If you have any questions, consult with the Penn Libraries to facilitate the implementation of appropriate descriptive metadata standards. All datasets will be published in ScholarlyCommons and reviewed as needed.
NIH Rigor and Reproducibility requirement

The research strategy is where you discuss the significance, innovation, and approach of your research plan. Let’s look at an R01, for example:

The new research strategy guidelines require that you:

- State the strengths and weakness of published research or preliminary data crucial to the support of your application
- Describe how your experimental design and methods will achieve robust and unbiased results
- Explain how biological variables, such as sex, are factored into research design and provide justification if only one sex is used
NEW ATTACHMENT FOR AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

From now on, you must briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

These include, but are not limited to:

- CELL LINES
- ANTIbodyES
- SPECIALTY CHEMICALS
- OTHER BIOLOGICS

Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.

DO NOT put experimental methods or preliminary data in this section.
NEW REVIEWER GUIDELINES

Here are the additional criteria the reviewers will be asked to use:

- Is there a strong scientific premise for the project?
- Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?

DO focus on authentication and validation of key resources

Reviewers will also be asked to comment on that new attachment (see Update 2)!
New age policy

• For application due dates on or after January 25, 2019 (one year from now), you must have a plan describing how participants across the lifespan will be included and justify the proposed age range of participants.

• Reviewers will consider whether the proposed age range is appropriate in the context of the specific scientific aims. Should the study be funded, keep in mind that your progress reports will include de-identified individual-level participant data on sex/gender, race, ethnicity, and age at enrollment (in units ranging from hours to years).
Vertebrate Animals Section changes

- A description of veterinary care is no longer required.
- Justification for the number of animals has been eliminated.
- A description of the method of euthanasia is required only if the method is not consistent with AVMA guidelines.
NIH checklist for animal research

1. Description of Procedures (Vertebrate Animals Section)
   - Describe the animals and their proposed use. Address the following for all species to be used:
     - __ Species
     - __ Strains
     - __ Ages
     - __ Sex
     - __ Total number of animals by species to be used
     - __ Concise description of proposed procedures on live animals (i.e., sufficient information for evaluation)
     - __ Source, only if dogs or cats are proposed

2. Justifications (Vertebrate Animals Section)
   - Provide justifications for:
     - __ Choice of species
       - Why research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro)

3. Minimization of Pain and Distress (Vertebrate Animals Section)
Human subjects

• Is it human subjects research?

Research Involving Private Information or Biological Specimens

Are the specimens/data obtained from living individuals?
- NO, individuals are NOT living
- YES, individuals ARE living

NOT Human Subjects Research

Are the specimens/data:
- Human cell lines obtained from a commercial provider (e.g., ATCC), or
- Human cells about which all information has been published; or
- Unidentifiable specimen/data obtained from a commercial provider; or
- Unidentifiable specimen/data obtained from an provider that is prohibited from releasing identifiers by established regulations or policies

- NO
- YES

Were/will the specimens/data (be) collected specifically for the proposed research through an interaction or intervention with living individuals?

- NO
- YES

NOT Human Subjects Research

Can the recipient link the specimens/data directly to identifiable living individuals?

- NO
- YES

Human Subjects Research

Can the provider link the specimens/data, directly or indirectly, to identifiable living individuals?

- NO
- YES

Human Subjects Research

Does the provider meet the definition of an “investigator” in the recipient’s research?

- NO, provider is “solely providing”
- YES, provider is collaborating in recipient’s research

Are the specimens/data provided with a code linking them to identifiable living individuals?

- NO
- YES

Human Subjects Research

Can the recipient readily ascertain the identities of the individuals to whom the specimens/data pertain? Examples of situations in which the recipient cannot link the specimens/data to living individuals include:
- the key to decipher the code is destroyed before the research begins; or
- the investigators and the holder of the key to the code enter into an agreement preventing the release of the key to investigators under any circumstances; or
- there are IRB-approved written policies in place preventing the release of the key under any circumstances; or
- there are other legal requirements prohibiting the release of the key under any circumstances.

- NO
- YES

NOT Human Subjects Research

Human Subjects Research
# Completing the PHS HS/CT Information Form – Exempt HS Research

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<th>Exemption 1</th>
<th>Section 1 Basic Information</th>
<th>Section 2 Study Population Characteristics</th>
<th>Section 3 Protection and Monitoring Plan</th>
<th>Section 4 Protocol Synopsis (Clinical Trials only)</th>
<th>Section 5 Other Clinical Trial Related Attachments (Clinical Trials only)</th>
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<td>Complete, if clinical trial</td>
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Clinical Trials

Decision Tree for NIH Clinical Trial Definition

Does the study involve human participants research?
- YES
- NO

Are participants prospectively assigned to an intervention?
- YES
- NO

Is the study designed to evaluate the effect of the intervention on the participants?
- YES
- NO

Is the effect being evaluated a health-related biomedical or behavioral outcome?
- YES

This study is a clinical trial.

The study is NOT a clinical trial.
Protocol support

- **Erin Schubert** erin.schubert@uphs.upenn.edu
- can help with developing protocols and data protection plans in all areas
• As always, and even more so now, get your grants in early!
Topical Presentation
Research Update:
PET Radiochemistry Program

Bob Mach, Ph.D.