Departmental Resources for Research Development

Beverly Collins
Amber Nestor
Erin Schubert

Our Goals

- To give you basic information about administrative processes involved in doing research and submitting grants at Penn
- To offer our help in these processes when possible and give you contacts for when you have questions.
TOPICS

Beverly Collins: **Grant preparation and submission**

Amber Nestor: **Budget development**

Erin Schubert: **Protocol development**

**Research resources**

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Grant preparation and submission

Beverly Collins

Grant Coordinator
Putting together a grant

I can help with administrative elements:
- Funding sources
- Biographical sketch
- Resources descriptions
- Collecting letters, signatures
- Information
- Reminder, go-between
- Proofreading

Where to get money?
- Professional Societies (RSNA, RRS, AUR, ASNR, SIR, etc.)
- Foundations (ACS, AHA, Komen, etc.)
- Government: NIH, DOD, CDMRP, etc.
Where to get money?

- **Penn sources**
  - McCabe Award [jr faculty only]
    - 1 year, $20k/$40k, 3-page writeup
  - University Research Foundation [faculty only]
    - $50k no salary, 1 yr, 3-page writeup, October 15

Where to get money?

- **Penn sources**
  - ITMAT Institute for Translational Medicine and Therapeutics)
    - 1-2 years, various amounts, 2-page writeup
  - Radiology ProDev (Protocol Development) fund
    - Offers scans and coordinator time
  - Various others on occasion, e.g.
    - Cancer Center
    - Lung Center
    - MSK
Where to get money?

- The Second Bank of the United States

420 Chestnut Street

Open to the public free of charge, housing a large collection of portraits of prominent early Americans painted by Charles Willson Peale and many others.

Where to get money?

Fourth mint, 1969
Independence Mall

1 of 4 in country, 1 of 2 that allows tours

1M coins in 30 mins
Submitting a Proposal

- 2 ways a grant may be submitted
  1. P.I. submits the grant directly to the funding agency.
  2. A representative of Penn submits the grant to the funding agency.

- Funding agency designates which way

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Submitting a Proposal

- RSNA’s application is submitted by the P.I. online through their website.

- But....
Penn’s review process

- EVERY external-funding proposal must be entered into Penn’s online grant application system (PennERA/PD)

Penn’s review process

- If the grant is administered by Penn, it does NOT need to go through PennERA. E.g.
  - ITMAT
  - Cancer Center
  - University Research Foundation
  - McCabe Faculty Award

- Pre-proposals and LOIs also usually do not go into PennERA, unless they include a budget or institutional signature.

- Everything else does.
In-house review process

- The proposal’s budget must undergo review by various offices in the University.
  - Radiology Grants Administration
  - Chair of Radiology
  - Med School Grants Office (ORSS)
  - University Office of Research Services (ORS)

This is all to protect you and the institution from legal issues regarding spending, etc.
- The grant, and the responsibility, falls on the institution. You’re a sharecropper.
- They will basically review the budget, not the science.
- However, reviewers may notice other errors, omissions, etc.
- This record will also be used in administering the grant post-award.
PD (Proposal Development)

- https://www.pennera.upenn.edu/

Penn's Electronic Research Administration System (PennERA) is the rule of web-based applications that encompass the entire life cycle of research projects. It enables researchers and administrators to efficiently manage their projects by providing a centralized platform for managing proposals, grants, and awards. PennERA is designed to support the entire research lifecycle, from proposal development to project management. To gain access to the PennERA application, please review the "Proposal and Grants" section of the website for general information and authorization forms.
PD (Proposal Development)

Penn’s review process

- For non-NIH proposals, set up PD using “generic” mode.
- Use the application provided by the funding agency and upload it to PD for institution review and approval.
- The funding agency will indicate whether the application is to be submitted by an institutional official.
Signature page

- If proposal is submitted by the PI, but requires institutional signatures (e.g. RSNA):
  - You will enter names of signatories to RSNA application site, then download the signature page.
  - You, your advisor, and the chair sign, then upload to PD.
  - When budget is approved, Penn rep will sign, and you can download completed page from PD and upload it to RSNA site.

RSNA Proposals

- RSNA deadline: Jan 15, 2020
  (Education grants due Jan 10)
  - Research Scholar Grant for jr faculty, $75K
    (1 nomination per institution: one-page abstract to me by Nov 22 for consideration)
  
  https://www.rsna.org/research/funding-opportunities/research-grants/research-scholar-grant
Penn’s review process: NIH

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You must use one of these submission options to access the application forms for this opportunity:

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.
Penn’s review process

- NIH proposals are created from the PD record; you **DO NOT** use ASSIST or grants.gov.

- Upload all the pieces into PD: biosketch, resources, bibliography, research plan, etc.

- PennERA compiles these into the NIH proposal.

- NIH proposals are submitted by the Office of Research Services, not the P.I.
Penn’s review process

- I can set up or help you set up the proposal in PD.
- I need:
  - What grant you are applying to
  - Proposal title
  - Dates or duration
  - Any subcontracts?
  - Human or animal subjects? Clinical trial (phase)?
  - NIH: Using any biohazards, human embryonic stem cells?

Once it is set up, you can upload files or send them to me to upload.

You will need to log into the proposal to certify some questions about the proposal (e.g. conflict of interest, foreign components, all researchers are authorized, etc.)
Penn’s review process

- You don’t need to enter the budget info into PD. We have people to do that for you.
- Amber Nestor handles all RSNA grants and many junior faculty submissions. Or you may be directed to another member of the department’s Research Administration.
- Ask me or Amber or Bill D’Arcy who you should work with on your budget.

Timeline

- The administrative (i.e. budget) part of the proposal should be submitted for Penn review 2 weeks before deadline.
- NIH grants should be FINALIZED by at least 3 days before the deadline.
Human Subjects: NIH

- Human subjects research, even if not a clinical trial, requires many documents to be uploaded, as well as enrollment estimates for various categories.
- If clinical trial (intervention), you also need the protocol.
- You do not need IRB approval at submission time.

Public-access requirement

- Publications resulting from government-sponsored research must be publicly accessible.
- Indicate the grant in the Funding Sources section of the manuscript.
- When published, ensure that the ms is uploaded to PubMedCentral.
- It must be public-access compliant for your next year of funding to be awarded.
- I can help with the process if needed.
Take-home points

- Grant-writing takes time and has a lot of pieces
- There is a Penn review process before submitting to sponsor
- There are people here to help
- Let me know as soon as you decide to apply for a grant

Budget

Amber Nestor
Grant Manager
Budget

- Contact – 6-8 weeks prior to due date
- Send guidelines/funding announcements for review
- Budget must be finalized 10-14 business days prior to due date

Budget

- PSOM Research Services requires NIH grants to be submitted for Pre-Review 5-7 business days prior to the due date
- Once Pre-Review is complete, your proposal must be routed to central Research Services
- Your science must be in FINAL format 3-5 business days prior to the due date - NO EXCEPTIONS!!
- Your proposal will be submitted by Radiology’s Pre-Award contact in central Research Services
What should be included?

- Personnel: % effort for each investigator
- Imaging: how many of what kinds of scans
- Supplies, equipment, animals, etc.
- Travel, for presenting results
- I can help with this if you are unsure!!

What else do you need to do?

- Budget justifications – if these are required, they must have detailed information about what you’re asking for! I can send samples of justifications if you are lost!
- Pay close attention to due dates for grants - specifically NIH grants!
Congrats! You’re funded... now what?

- All funds come through Radiology
- No pre-award costs are allowed, unless noted in the NOGA or award letter
- Spending cannot occur prior to start date of grant
- Account numbers are issued once the grant is awarded.

Finally....

- Please DO NOT submit grants on your own!! Every grant that you apply for must have institutional review.
- Some sponsors require signature pages
- NIH requires submission be done by an authorized University official!
Protocol Development

Erin Schubert
Administrative Director, PET Center

Investigator Initiated

- Idea → Grant → Protocol
- Start planning your protocol from the beginning
- Sections of the protocol will overlap with grant requirements
- IRB submission and review can take 6-8 weeks from submission to approval
- IND submission can take additional time
Plan Your Grant

- Planning for the human subjects protocol early will aid in grant preparation
  - Helps motivate grant aims
  - Developing a budget and budget justifications
  - Evaluating necessary staff and co-investigators requiring funding
  - Human subject protections write up

Strategic Planning

- NIH grants often require IRB approval as part of JIT submissions
- Avoid delays in study start up once you receive funding
- Institutional opportunities may exist to start collecting pilot data prior to notice of award
- Multiple UPenn regulatory committees (IRB, RRSC, CTSRM)
Protocol Building Blocks

- Background and Scientific Rationale
  - What is the purpose of the proposed research? What is the value added?

- Objectives
  - What do you hope to learn from the proposed research?

- Study Design
  - What is your plan for meeting the study objectives?

Protocol Building Blocks

- Participant selection
  - What subject population do you plan to study?

- Recruitment
  - How will you get access to your subject population? Does this require additional collaborators?

- Investigational agent?
  - Does the study require an IND?
Protocol Building Blocks

- Procedures
  - What research procedures will the study include? Who will perform the procedures?
- Risks
- Statistical Plan
  - How will you analyze your study results?

IND Considerations

- Does your study involve an investigational drug?
- Is the drug currently made at Penn or by another supplier or does it need to be developed?
- Will your study require a new IND or does Penn already have an active IND?
IND Building Blocks

- Background and Investigational Plan
- Pharmacology and Toxicology
- Previous Human Experience
- Biodistribution and Dosimetry
- Chemistry, Manufacturing and Controls
- Protocol and Investigator Information

Key Contacts for Protocol/IND

- Erin Schubert – Protocol, IND, Regulatory document development and submission
- Kathleen Thomas and Patty Atkinson - Radiology IND support office, handles all IND submissions and monitoring
- Sharon Lee – Cyclotron contact for development of drug synthesis, validation testing and CMC creation
Clinical Trial Planning

- Industry sponsored research is heavy on start up – can take 3-6 months
- Work with finance group and research coordinator or manager early to develop the budget
- Non-refundable start up fee of $15,000 must be included in the budget

Feasibility Review

- Is the research technically feasible? Do we have the resources needed?
- Do we see the patient population at Penn?
- Are collaborations with other departments needed?
- Does the budget include support for staff and necessary services?
It takes **time**, **resources** and a **team** to start up a trial!

**Resources for Budget Development**

- Radiology Research Administration
- Office of Clinical Research CT unit
- Cost finder
  - [https://www.med.upenn.edu/apps/ocr/costfinder](https://www.med.upenn.edu/apps/ocr/costfinder)
- Radiology service centers/IDS/CHPS
Clinical Trial Start Up

- Budget negotiation with sponsor
- CTA review by ORS and OCR CT contract unit
- Regulatory documents/ICF to sponsor
- Regulatory submissions at Penn
- Central IRB only allowed for Phase 3
- CTA fully executed/final ICF review

Once the trial is open

- Identify and train staff needed to implement trial
- Interacting with the sponsor: Data entry, queries, AE reporting, monitoring, image uploads
- PI oversight is critical
- Tracking milestones and billing are key
Research Resources

- Protocol Development Funding (Prodev)
  - Applications are reviewed quarterly (March, June, September, December)
  - Purpose: to provide financial and personnel support to Investigators to collect pilot data for grant submissions
RADCORE Support

- Fee for service offered through the Clinical Imaging Core (CIC) service center
  - Study start-up activities (IRB submission, budget prep, etc...)
  - Regulatory management
  - New employee training
  - Contact Kathleen Thomas with questions

Key Links - Research at Penn

- IRB: https://hsera.apps.upenn.edu
- RRSC: https://ehrs.upenn.edu/radiation-safety/topics/research
- CTSRMC: http://www.ctsrmc.org/
- CAMRIS: https://www.med.upenn.edu/camris/
- OCR: https://www.med.upenn.edu/ocr/
Radiology Service Centers

- RADCORE (Clinical Imaging Core)
  - Kathleen Thomas
  - Kathleen.thomas@pennmedicine.upenn.edu
  - 215-746-0352

- PET/Nuc Med Service center
  - Erin Schubert
  - Erin.schubert@pennmedicine.upenn.edu
  - 215-573-6569

- CT: CACTIS (Center for Advanced Computed Tomography Imaging Services)
  - Lisa Angilletta
  - Lisa.angilletta@pennmedicine.upenn.edu
  - 215-662-4595

- MRI: CAMRIS (Center for Advanced Magnetic Resonance Imaging and Spectroscopy)
  - Shannon Long
  - Shannon.long@pennmedicine.upenn.edu
  - 215-573-9765

- Ultrasound
  - Susan Schultz
  - Susan.schultz@pennmedicine.upenn.edu
Key Links - Research at Penn

- PennERA
  https://www.pennera.upenn.edu/
- Office of the Vice Provost for Research
  Information about Penn resources, such as
  Electronic Lab Research Notebook
  https://research.upenn.edu/about/research-excellence-initiative/

People in department

- Beverly Collins: beverly.collins@uphs.upenn.edu, 215-615-0429 grant funding, proposal development
- Amber Nestor: amber.nestor@uphs.upenn.edu 215-349-8421 budget development
- Erin Schubert: erin.schubert@uphs.upenn.edu protocol development
- Kathleen Thomas: kathleen.thomas@uphs.upenn.edu 215-746-0352 research coordinator requests
- Bill D’Arcy: william.d’arcy@uphs.upenn.edu 215-329-8423 Business Administrator for grants, pre- and post-award