Departmental Resources for Research Development

Beverly Collins
Amber Nestor
Erin Schubert
TOPICS

Beverly Collins: Grant-preparation and submission

Amber Nestor: Budget development

Erin Schubert: Protocol development
Putting together a grant

I can help with:

- Funding sources
- Biographical sketch
- Resources descriptions
- Collecting letters, signatures
- Information
- Noodge, go-between
- Proofreading
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
Penn’s review process

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

Gender-differences of intracranial arterial wall changes using vessel wall MRI
JAE W SONG - 4452 - RA Radiology (RSNA RES & EDUC FDN)

Setup Questions

Important: If this is a non-S2S Child Submission record, change screen template to UPENN - Non-Competing UPENN - Supplemental (non-S2S) Template and let screen refresh before answering any questions on this tab.

If this is an S2S submission, do NOT change the default screen template without first contacting PennERAhelp@lists.upenn.edu.

Each proposal is broken down into several sections based upon what the sponsor and your institution require. Once each section is completed, indicate so by checking the Complete checkbox in the upper right corner of that section. When all sections have been completed, you will be able to produce the final copy of your proposal.

Submission Mechanism/Form Information

Proposal Sponsor: RSNA RES & EDUC FDN
Is this a Flow Through Project?: No
Please select a Submission Mechanism/Screen Template: UPENN - Generic Template
Is this a US federal sponsored project?: No
Will this be a proposal to PHS, NIH or one of the branches of NIH?: No

Deadline Information

Deadline Type: Electronic Receipt
Deadline Date: 15-Jan-2019
Penn’s review process

- For non-NIH proposals, use the application provided by the funding agency and upload to PD for institution review and approval.
- The funding agency will indicate whether the application is to be submitted by an institutional official.
- (NIH proposals are created from the PD record; you do not use the NIH application package.)
Penn’s review process

- I can help you set up the proposal in PD.
- 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 most resident proposals.
The administrative (i.e. budget) part of the proposal should be submitted for Penn review 1-2 weeks before deadline.
RSNA Proposal Instructions

- RSNA deadline: Jan 15, 2019
- Penn budget deadline: Jan 8
- You will need a signature from Penn
A. Signatures

Enter the names and contact information for each individual that will sign the completed, printed application. Hand signatures only. No stamps, etc.

I/we recommend the applicant as an RSNA Research Resident/Fellow Grant recipient. By checking the items below (x), I/we affirm the following:

☐ The grant application form has been completed to the specifications required by the RSNA Research & Education Foundation, and that the information submitted is accurate and true;
☐ Arrangements for the outlined program have been made and the funds and support services described are available;
☐ The terms and conditions as stated in the Policies and Procedures section of this application form are acceptable according to the policies of the host institution and they can and will be honored;
☐ The funds will be spent in the manner prescribed;
☐ The principal investigator will receive a minimum of 50% protected time to devote to the research project;
☐ The principal investigator and the sponsoring department agree to carry out the activities described in this application within the time specified;
☐ The principal investigator will submit a progress report halfway through the project, and a final report at the completion of the project.

Upon completion of the residency/fellowship, the principal investigator will be considered for a faculty position. If a faculty position is not available, we will support the applicant’s efforts to locate an academic position at another institution.

Department Chair

Mitchell Schnall, MD, PhD

12/22/17

Date

Scientific Advisor

Teresa Gade, MD, PhD

19 December 2017

Date

Grant Administrator

Alice Dunleavy, Associate Director Office of Research Services

Date

Principal Investigator (Applicant)

Brian Park, MD

12/18/17

Date
RSNA Signature page

- 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.
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
Speaking of budgets...

- The First Bank of the United States

128 South 3rd Street

GREEK REVIVAL
Speaking of budgets...

- The Second Bank of the United States

420 Chestnut Street

**GREEK REVIVAL**

The structure is open to the public free of charge and serves as an art gallery, housing a large collection of portraits of prominent early Americans painted by Charles Willson Peale and many others.
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
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
Protocol Development

- Idea $\rightarrow$ Grant $\rightarrow$ Protocol
- Start planning your protocol from the beginning
- Many sections of the protocol will overlap with required grant sections
- 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, CTSRMC)
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 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
Key Links - Research at Penn

- **IRB**: [https://hsera.apps.upenn.edu](https://hsera.apps.upenn.edu)
- **RRSC**: [https://ehrs.upenn.edu/radiation-safety/topics/research](https://ehrs.upenn.edu/radiation-safety/topics/research)
- **CTSRMC**: [http://www.ctsrmc.org/](http://www.ctsrmc.org/)
- **CAMRIS**: [https://www.med.upenn.edu/camris/](https://www.med.upenn.edu/camris/)
- **OCR**: [https://www.med.upenn.edu/ocr/](https://www.med.upenn.edu/ocr/)
Key Links - Research at Penn

- PennERA: https://www.pennera.upenn.edu/
- RSNA grants: https://www.rsna.org/en/research/funding-opportunities/research-grants
People in department

- **Beverly Collins**: grant funding, proposal development
- **Amber Nestor**: budget development
- **Erin Schubert**: protocol development
- **Kathleen Thomas**: research coordinator requests
- **Bill D’Arcy**: Business Administrator for grants, pre- and post-award