

What types of support do clinical and translational researchers need during proposal preparation?

Jing Liu, PhD

**Michigan Institute for Clinical and Health Research,
University of Michigan, Ann Arbor, MI, USA**

Why should we know?

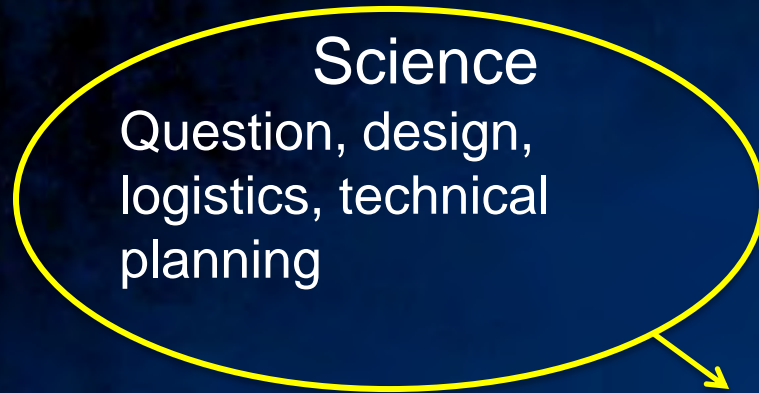
What are research development best practices during grant proposal preparation?

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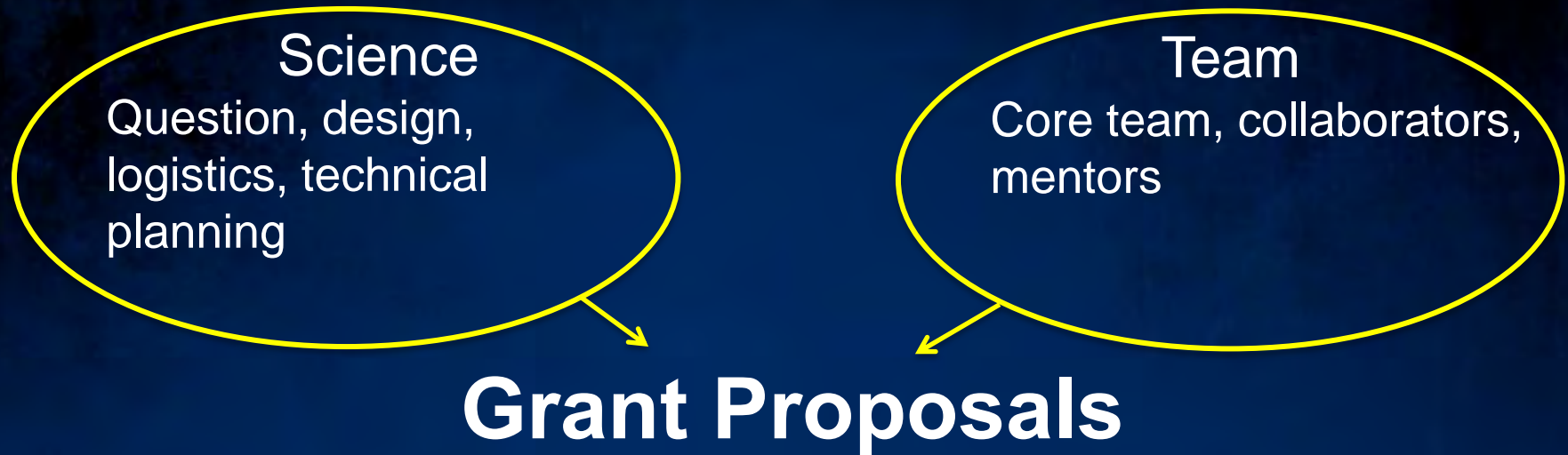
How do we develop research infrastructure and workforce for the future?

What goes into proposal development?

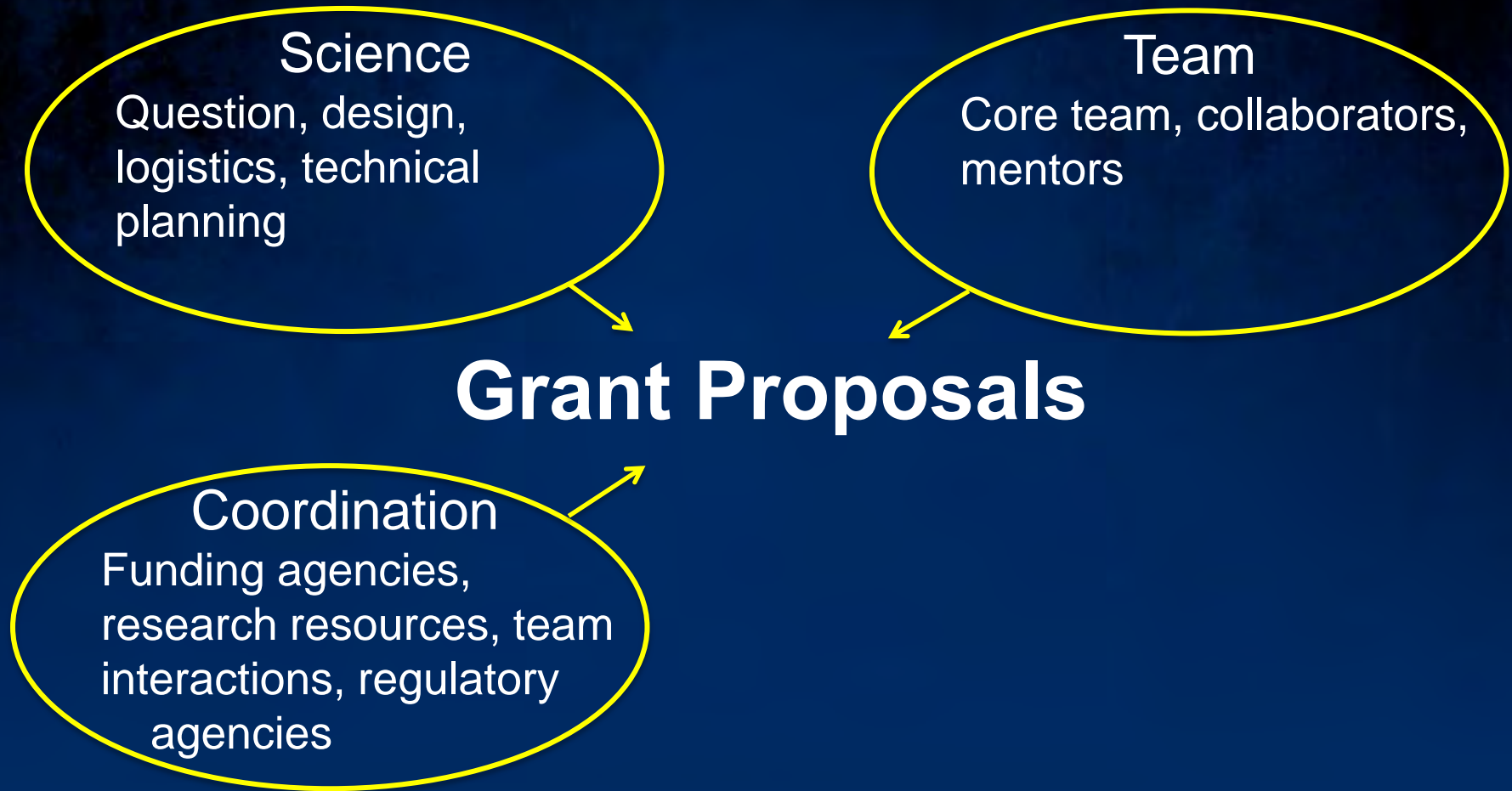


Grant Proposals

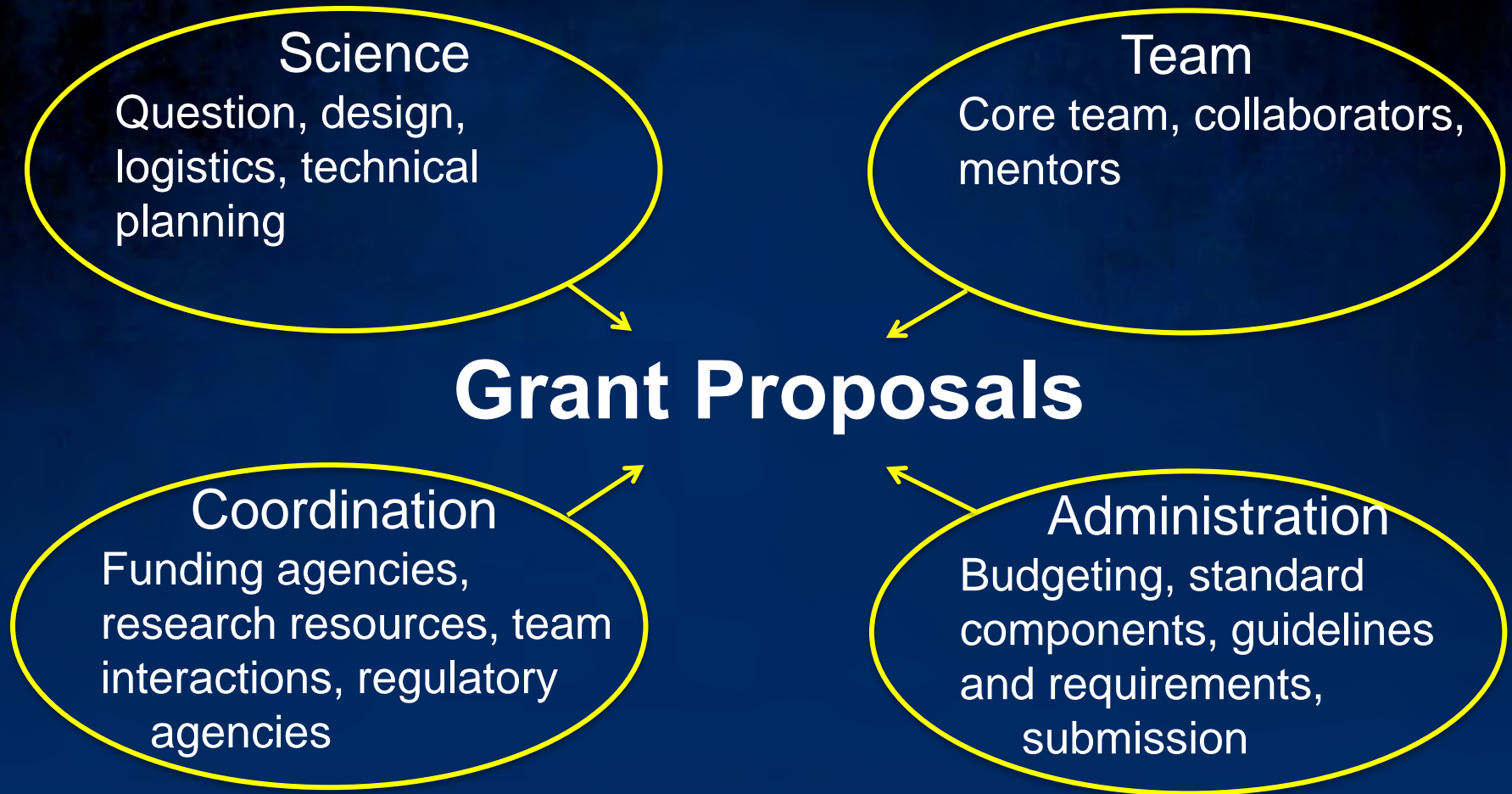
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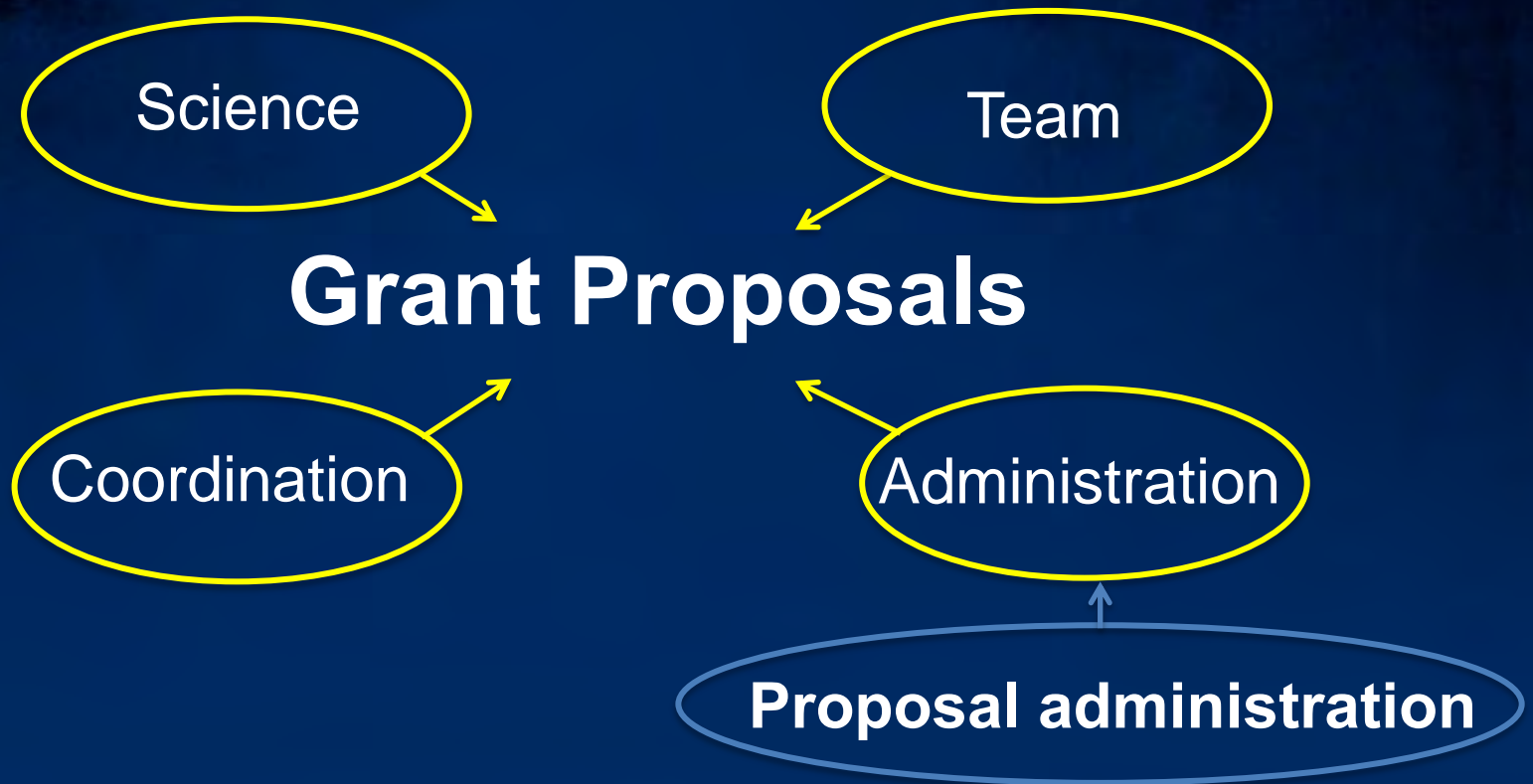
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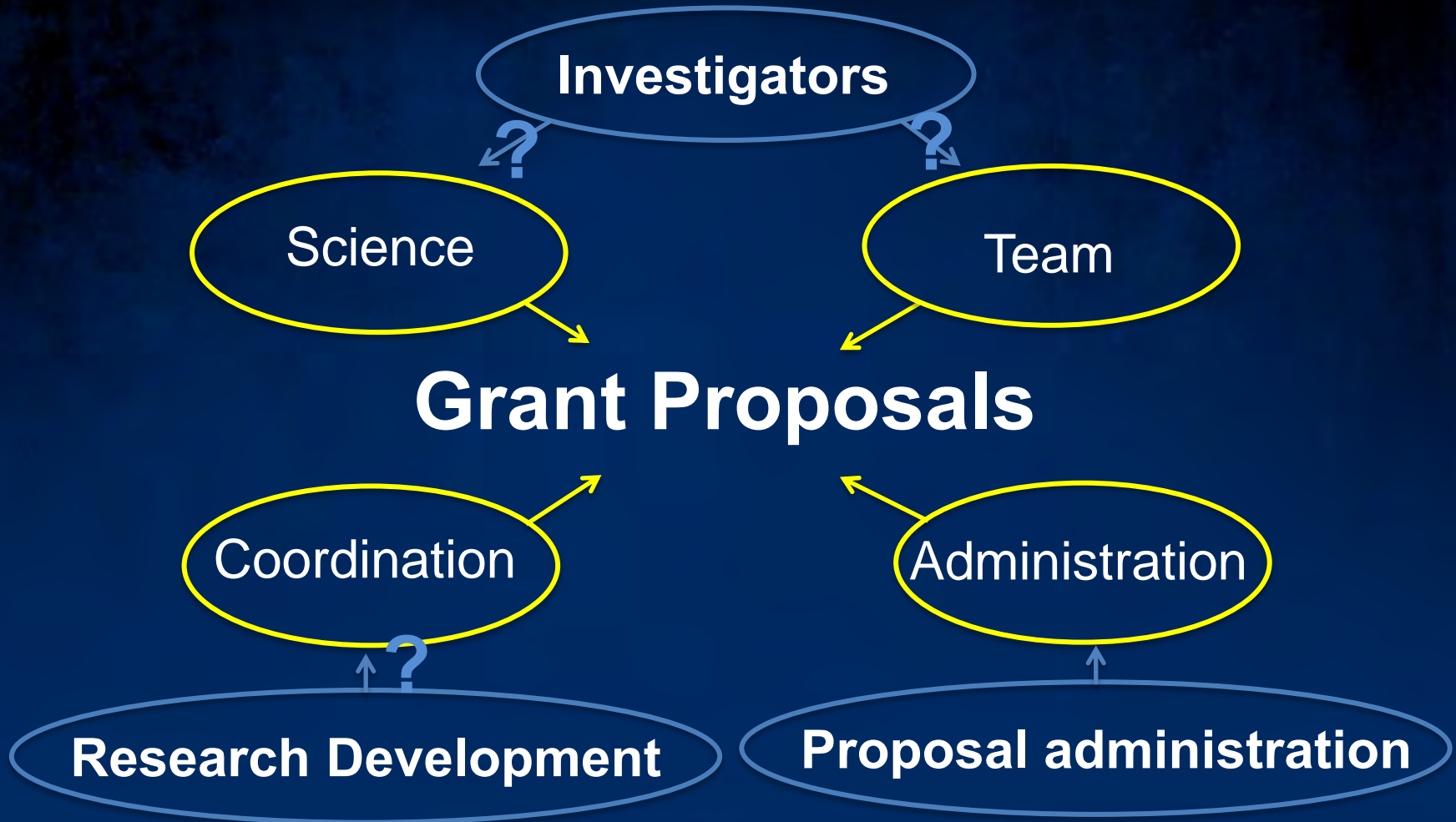
What goes into proposal development?



Who supports each part?



Who supports each part?



What is typically offered now?

**What are the needs of the
investigators?**

What are typically offered now?



National Organization of Research Development Professionals

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- [Research Development Officer \(2 positions available\)](#), University of California, Merced (Posted 03-03-15)
- [System Director, Office of Sponsored Programs](#), CHRISTUS Health (Posted 03-03-15)

What are typically offered now?

I went through a number of the job postings that appeared at NORDP website since 2009, and categorized the pre-award support into a few major classes.

Final sample: 56 job postings.

(Special thanks to Holly Falk-Krzesinski for archiving and sharing all these postings)

What are typically offered now?

Job postings examined: 56

Identify funding opps (39)
Review/edit proposals (30)
Coordinate complex proposals (27)
Develop and provide training (21)
Draft non-technical components (19)
Facilitate collaborations (16)
Provide template language (15)
Coordinate submission (15)
Budget (3)
Mentor on study design and
Idea development (1)



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Mentor on study design and
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10/56 positions required a background of PhD and/or research

Michigan Institute for Clinical and Health Research



What is MICHR

MICHR was created in 2006, awarded a \$55M Clinical and Translational Science Award from the NIH in 2007, and renewed in 2012. It is part of a national consortium of 62 institutions working together to accelerate discoveries toward better health.

MICHR At A Glance

Research Guidance and Support

Idea and grant proposal development

Biostatistics

Research Monitoring

Regulatory Support

Bioinformatics

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Study participant recruitment

Biorepository

Clinical Research Facility

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Workforce Training

Workshops and symposia
Summer courses
Degree programs
Career development Awards
Mentored, intensive programs

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UNIVERSITY OF MICHIGAN

Idea and grant proposal development

1. The structure of our unit that provides consultation in idea and proposal development
2. The impact of our service
3. Areas in which investigators need support from our unit

Idea and grant proposal development

1. The structure of our unit that provides consultation in idea and proposal development

Idea and grant proposal development

Research Development Core (RDC)

RDC Offerings

Consultation: research ideas and grant proposals

Editing: grant proposals



RDC Team

Two key consultants (senior faculty)

Staff specialists

Biostatisticians (faculty and staff)

**Ad hoc consultants with content expertise
(faculty and staff)**

RDC Services

We provide consultation to...

- Clinical, translational and basic research
- All types of grants: federal, foundation, pilot, training grants, center grants, clinical trials...
- One hour meeting, with before-meeting informal consultation and after-meeting follow-up

RDC Services

When investigators

*Have an idea for
a research proposal*

RDC

- *Helps improve study design, biostatistics*
- *Helps building collaborations*
- *Provides advice on funding sources and submission strategies*
- *Connects investigators to MICHHR research services and other research resources*



"My project is simply this. I want to find out once and for all whether there's any truth in the belief that money can't buy happiness."

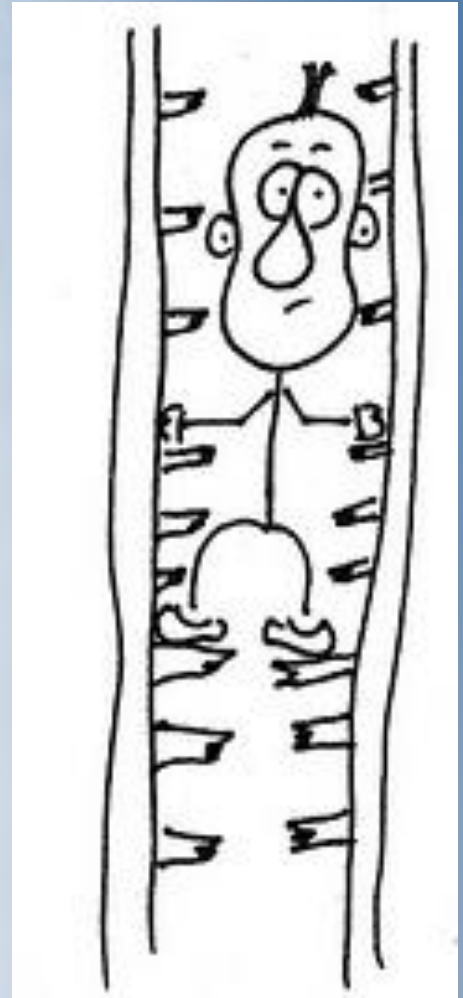
RDC Services

When investigators

Plan career development grants

RDC

- *Helps develop career development plans and mentoring plans*
- *Connects investigators to potential mentors*



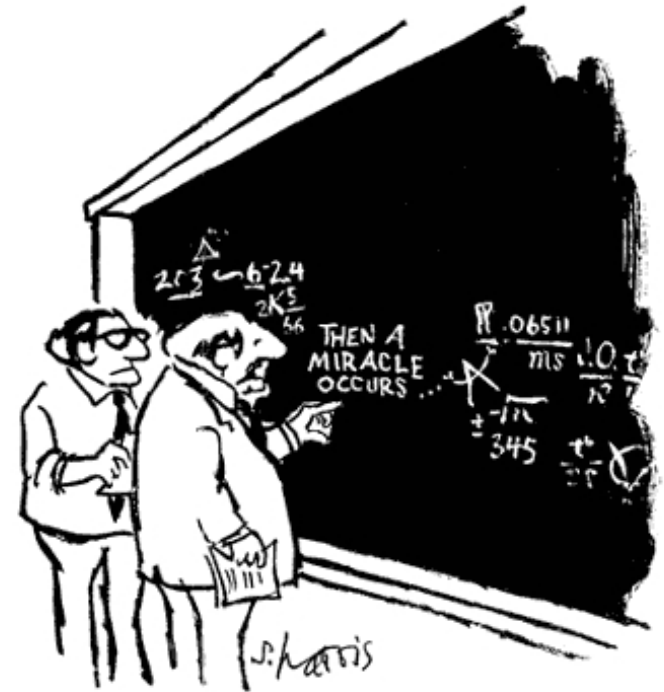
RDC Services

When investigators

*have a proposal in
near-final form*

RDC

- *Provides grant editing service*



"I think you should be more explicit here in step two."

RDC Services

When investigators

*Consider proposal
resubmission*



Dear Chemist,
Although your grant application
was denied, we would still like to
make a contribution to your research.
That's why we printed this rejection
letter on a piece of filter paper.

RDC

- *Helps address all aspects of reviewer comments, including study design, biostatistics, study team composition, career development plan, and research resources*

Idea and grant proposal development

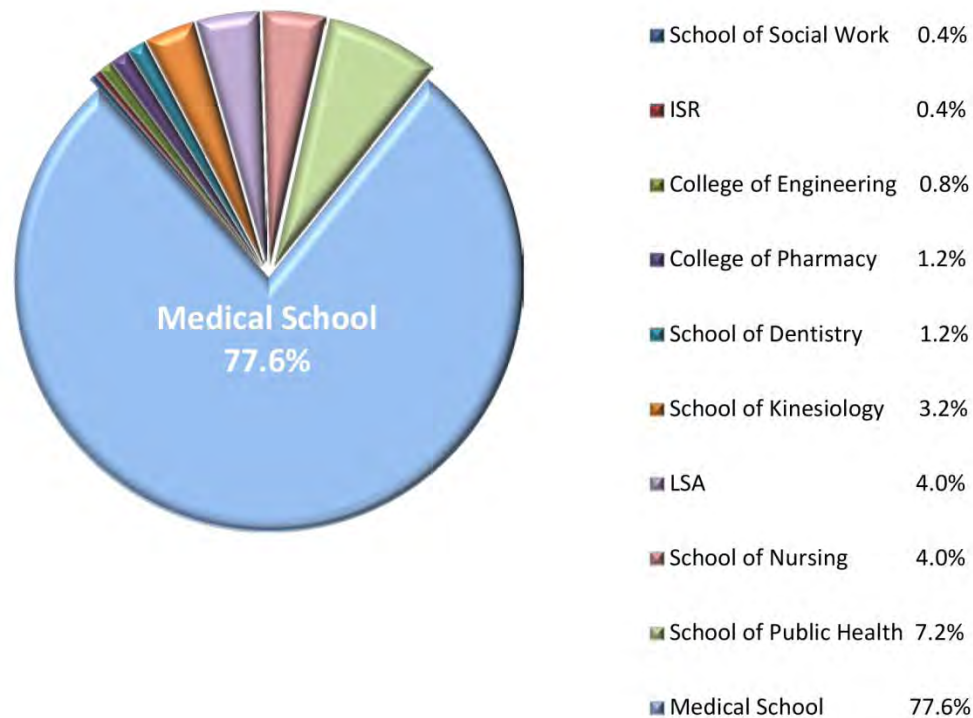
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2. The impact of our service

RDC's Reach

January, 2011 – present

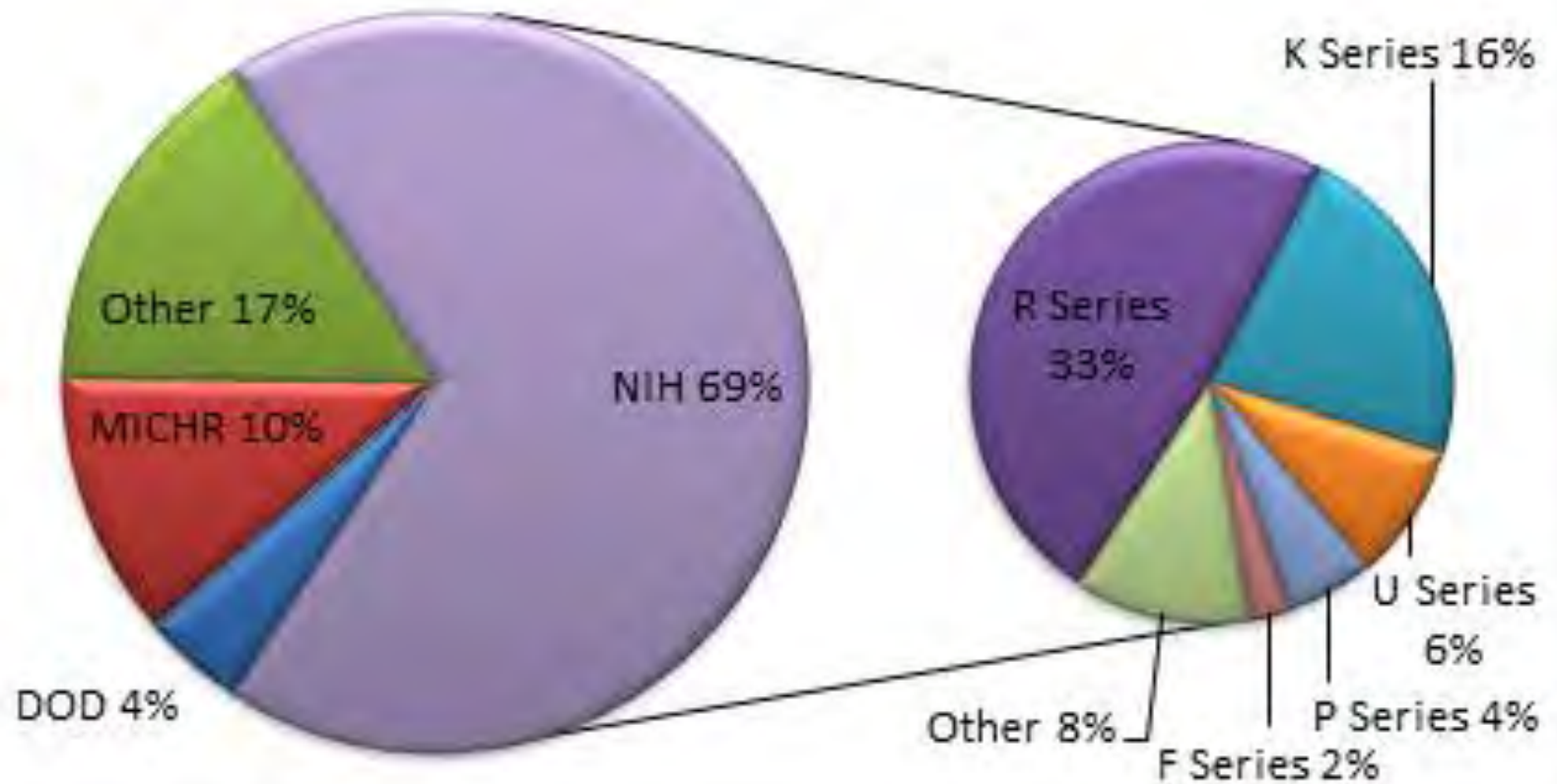
- 336 Consultations
- 73% Junior vs. 27% Senior Investigators
- 59 unique departments

Customers by College/School



Grant Mechanisms

January 1, 2011 – May, 2013



Investigator Feedback

- 95% of investigators report that RDC has impacted their proposals moderately to very much
- 92% of investigators report that it is very likely that they will use or recommend RDC in the future

Impact of our consultation

Difficulty in assessing impact that highlights common issues when we determine best practices in research support.

- 1. Biased sample: those who come to us are either struggling, or extremely well organized.**
- 2. We sometimes advise people not to submit, or to make major changes to the proposals.**
- 3. There is no guarantee that any investigator incorporates our recommendations.**
- 4. The effect of our consultation may also show in other, similar proposals that the investigators write.**

Impact of our consultation

Method:

1. We collected investigators' biosketch before the proposal consultation and 1-2 years after their RDC consultation.
2. We recorded new grants that may have been benefitted from the consultation.
3. We determined whether the awarded proposals were closely related to those discussed with RDC: same proposal and same funding agency? Same proposal but different funding agency? Related but not identical proposal?

Impact of our consultation

- # of investigators in sample: 59
- # (%) with new grants 45 (76%)
- # of new grants (average per person): 100 (1.7)
- # of new grants where a consultee is a PI or co-PI: 66
- # of new grants where a consultee is a co-I: 34
- # of new training grant (K12, etc.) trainees: 3
- # of federal grants: 34
- # of foundation or industry grants: 36
- # of internal grants: 30

Impact of our consultation

of new grants, same proposals as discussed with RDC,
same funding agencies: 14

of new grants, same proposals as discussed with RDC,
different funding agencies : 9

of new grants, slightly different proposals as discussed
with RDC: 6

Yield: 29 proposals for 59 investigators, or 50%

Impact of our consultation

Collaborations:

We followed up with 14 investigators who received specific recommendations during 2013 for collaborators and mentors.

7 worked with collaborators or mentors as we recommended.

They also contacted 9 other potential collaborators or mentors that we recommended but ended up not working together (due to funding, timing, people leaving the institution, etc).

Idea and grant proposal development

1. The structure of our unit that provides consultation in idea and proposal development
2. The impact of our service
3. Areas in which investigators need support from our unit

Areas that we consult with

Study design

Career direction

Biostatistics

**Submission/resubmission
strategy**

**Mentoring and
partnership**

Regulatory issues

Funding sources

**Research logistics: recruitment, study management,
preliminary data, business development, etc.**

Areas that we consult with

The investigators are the experts of their own science, but we know what a good proposal looks like.

We also know the resources.

What support do investigators need?

Sample: 124 investigators (98 junior, 26 senior)

Method: compare the areas where they would like to receive help, and the areas where help was actually given.

What did the investigators ask?

Junior Investigators (98):

Advice sought

Study design	68%
Biostatistics	42%
Funding sources	30%
Mentoring/partnership	29%
Career direction	27%
Sub/resub strategy	22%
Regulatory issues	5%

What did the investigators receive?

Junior Investigators (98):

	Advice sought	Advice given	Change in content
Study design	68%	70%	60%
Biostatistics	42%	41%	35%
Funding sources	30%	45% (p<0.001)	
Mentoring/partnership	29%	63% (p<0.0001)	
Career direction	27%	38% (p=0.01)	28%
Sub/resub strategy	22%	37% (p<0.001)	
Regulatory issues	5%	10%	

Scientific Content

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The Research Team

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What did the investigators receive?

Junior Investigators (98):

1. How to best answer the scientific question.
2. How to build the best research team.

Where and how to submit

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Career direction

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Junior Investigators (98):

1. How to best answer the scientific question.
2. How to build the best research team.
3. Where and how to submit proposals.
4. Career planning

What Scientific Questions to Pursue?

Junior Investigators (98):

	Advice given	Change in content
Specific Aims	43%	38%

What did the investigators receive?

Junior Investigators (98):

1. The scientific questions that they should ask
2. How to best answer the scientific question.
3. How to build the best research team.
4. Where and how to submit proposals.
5. Career planning

What did the investigators ask?

Senior Investigators (26):

	Advice sought	Junior Investigators
Study design	73%	68%
Biostatistics	46%	42%
Funding sources	31%	30%
Mentoring/partnership	35%	29%
Career direction	12%	27%
Sub/resub strategy	31%	22%
Regulatory issues	15%	5%

What did the investigators receive?

Senior Investigators (26):

	Advice sought	Advice given	Change in content
Study design	73%	65%	58%
Biostatistics	46%	42%	38%
Funding sources	31%	46%	
Mentoring/partnership	35%	62% (p<0.01)	
Career direction	12%	8%	4%
Sub/resub strategy	31%	35%	
Regulatory issues	15%	8%	

What did the investigators receive?

Senior Investigators (26):

	Advice sought	Advice given	Change in content
Study design	73%	65%	58%
Biostatistics	46%	42%	38%
Funding sources	31%	46%	
Mentoring/partnership	35%	62% (p<0.01)	
Career direction	12%	8%	4%
Sub/resub strategy	31%	35%	
Regulatory issues	15%	8%	

What Scientific Questions to Pursue?

Senior Investigators (26):

	Advice given	Change in content
Specific Aims	42%	38%

What did the investigators need?

All Investigators:

1. The scientific questions that they should ask
2. How to best answer the scientific question.
3. How to build the best research team.
4. Where and how to submit proposals.
5. Career planning (for junior investigators).

What can we offer?

Our conclusion

The scientific questions that they should ask

How to best answer the scientific question.

How to build the best research team.

Where and how to submit proposals.

Career planning (for junior investigators).

RD main duties now

Identify funding opps

Review/edit proposals

Coordinate complex proposals

Develop and provide training

Draft non-technical components

Facilitate collaborations

Provide template language

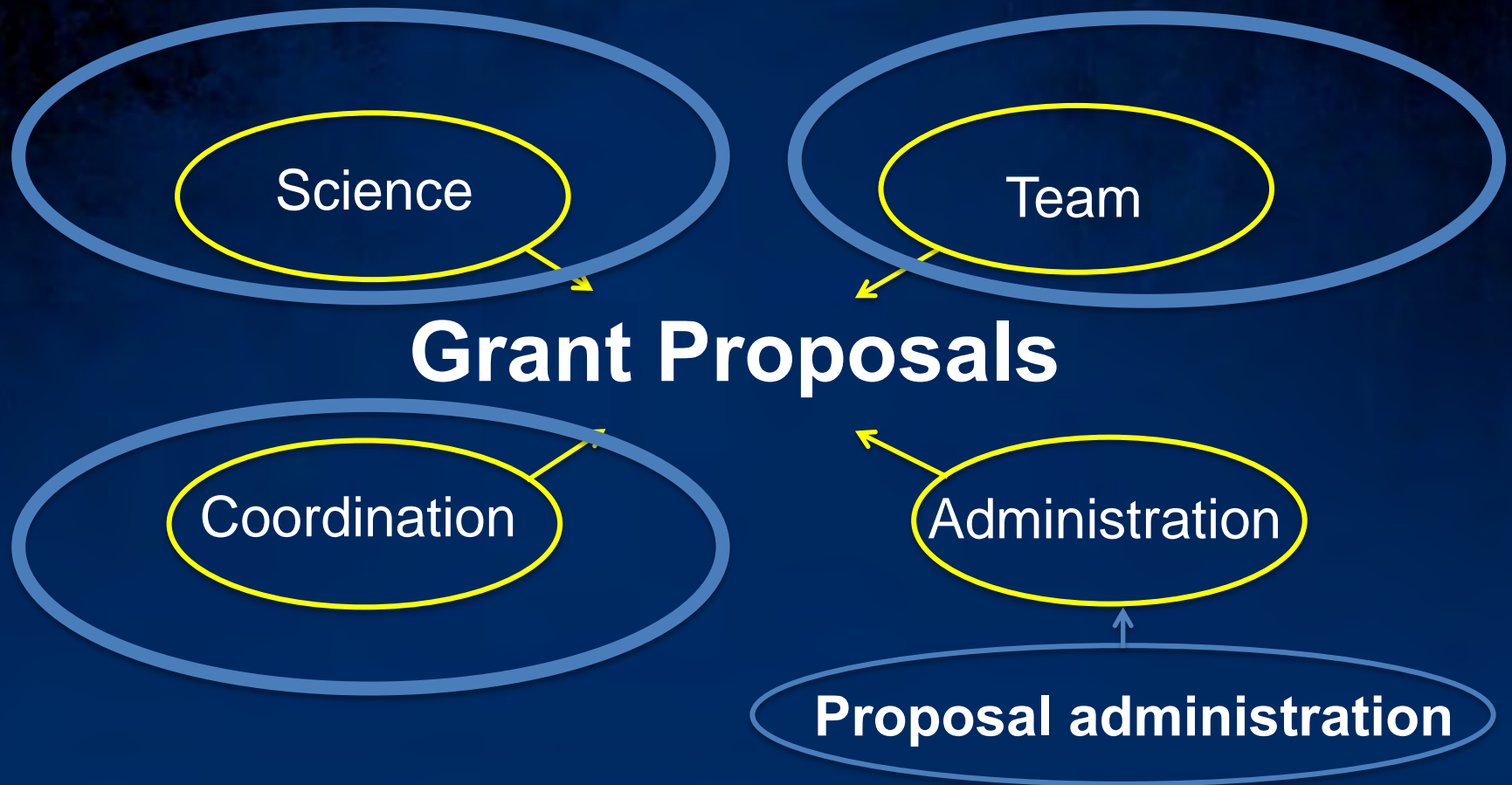
Coordinate submission

Budget

Mentor on study design and

Idea development

Where do investigators need support?



Recommendation

Don't forget the fundamentals.

Another Example

The departmental review program at Psychiatry Department,
University of Pittsburgh

Acad Psychiatry (2014) 38:5–10
DOI 10.1007/s40596-013-0027-1

EMPIRICAL REPORT

Using Peer Review to Improve Research and Promote Collaboration

David J. Kupfer & Anneliese N. Murphree &
Paul A. Pilkonis & Judy L. Cameron & Rosary T. Giang &
Nathan E. Dodds & Kasey A. Godard & David A. Lewis

Another Example

The departmental review program at
Psychiatry Department, University of Pittsburgh

Focusing on scientific content and building the
right team.

Whopping success: in recent years it takes 10%
of all NIH funding to all Psychiatry departments in
the nation.

What We Needed to run RDC

A small core group of experienced scientists and staff specialists

A small number of ad hoc consultants

Collaboration with campus-wide research support programs

Why a Small Group could Work

Good science and good investigators have common characteristics

Is the scientific question meaningful and impactful?

Does the study design answer the question?

Does the study team have the right expertise and work well together?

Is the investigator's career going to the right direction?

Future Directions for RDC

Support more investigators

Support a wider range of research proposals

Help people who are successful to be more successful

What did the investigators need?

Junior and senior Investigators both received guidance during proposal preparation in the following areas:

- 1. The scientific questions that they should ask**
- 2. How to best answer the scientific question.**
- 3. How to build the best research team.**
- 4. Where and how to submit proposals.**

Junior Investigators only:

Career planning

Continued Development of Expertise

Why would *independent* investigators still need support on the fundamentals?

- 1. The training process of research “sense” is not a formal one and it depends a lot on each individual and their mentors.**
- 2. Professionals need continued support and training.**

**The role of research development professionals?
Can we help formalize this training process?**

Evidence-based best practices

Today's research environment:

1. Tight funding
2. The society and the government demand for higher impact
3. Knowledge and methodology explosion calls for more effective research models
4. Intrinsic issues: lack of reproducibility, research integrity...

Research Irreproducibility



[Nature Special: Challenges in irreproducible research](#)

Journals, **research** laboratories and institutions and funders all have an interest in tackling issues of **irreproducibility**. We hope that the articles contained in this ...

www.nature.com/nature/focus/reproducibility/



[In science, irreproducible research is a quiet crisis - Ideas - The](#)

Mar 19, 2015 ... Unless **researchers** point out the limitations of one another's work, the ... how much **research** is **irreproducible** — and why — and are looking for ...

www.bostonglobe.com/ideas/2015/...irreproducible-research.../story.html

[Announcement: Reducing our irreproducibility : Nature News ...](#)

Apr 24, 2013 ... Over the past year, Nature has published a string of articles that highlight failures in the reliability and reproducibility of published **research** ...

www.nature.com/.../announcement-reducing-our-irreproducibility-1.12852



[Irreproducibility in Life Science Research: A Pervasive Problem](#)

Reproducibility is the foundation of life science **research**, yet far too often, the inability to reproduce experimental data has resulted in the invalidation of **research** ...

fkhealth.com/.../irreproducibility-in-life-science-research-a-pervasive-problem/

[Irreproducible Experimental Results](#)

Based on statistical simulations, Ioannidis argued that, for most study designs and settings, it is more likely that a **research** outcome is false than true. He pointed ...

circ.ahajournals.org/content/125/10/1211.full

[The Global Biological Standards Institute Engages Life Sciences ...](#)

The Global Biological Standards Institute Engages Life Sciences Community to Address **Irreproducibility** of Research Findings. ~ The causes are multifactorial ...

www.gbsi.org/.../global-biological-standards-institute-engages-life-sciences-community-address-irreproducibility-research-findings/



[Dealing with Irreproducibility | The Scientist Magazine®](#)

Apr 8, 2014 ... **Researchers** discuss the growing pressures that are driving ... and fraud, and general problems of data **irreproducibility**, spurring the National ...

www.the-scientist.com/?articles.view/articleNo/...Irreproducibility/

The Role of Research Development

Many opportunities to shape research for the future

Be conscious about best practices

Use rigorous research to examine our own work