Stretching the Rubber Band: Approaches that Meet Research Development Goals with Limited "Touch Time"

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DEFINITION

Lower Touch:

Any approach that has substantially decreased the amount of time a person or office was spending on an activity

OR

allowed a research development professional or group to accomplish something that would have otherwise been too time intensive.

Presentation Goals

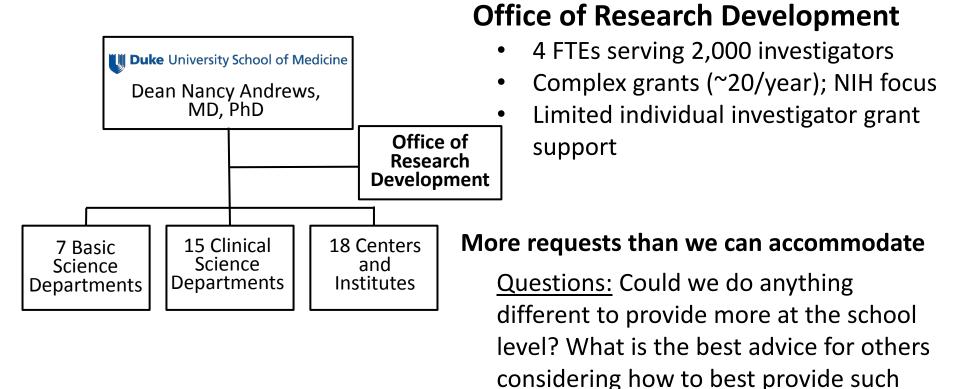
- Provide some context about the specific situation that sparked interest in developing a lower touch approach
- Define the original or "higher touch" setting (if applicable) and "lower touch" solution
- Share experiences with implementing and evaluating the approach
- General considerations and advice
- Cross-cutting themes

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Proposal Development Support for Individual Investigator Grants

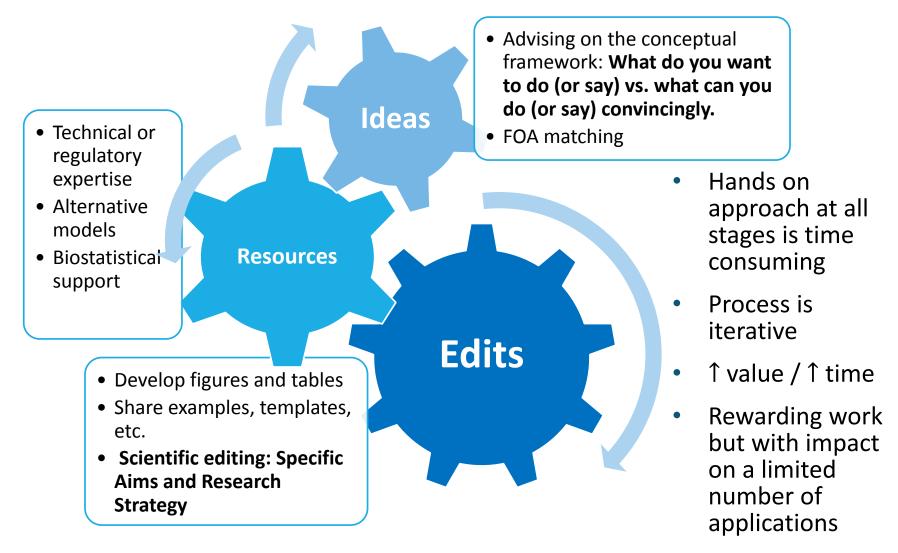
JENNIFER REININGA-CRAVEN, PHD

Setting and Demand



support locally?

Higher touch proposal development workflow



A Lower Touch Approach:

Strategically Targeting the Resubmission Step

APPROACH OVERVIEW LINEAR WORKFLOW **Review Summary Statement**, Identify criticisms and planned application, and response responses Evaluate the proposal and responses for common issues and identify Diagnose problems and identify solutions; add value advising as an solutions objective 3rd party; use rubric to focus our work Can be more hands off Edit to integrate changes and finalize Edit priority targets, e.g., proposal for submission Introduction, and do more as time allows

• Provide feedback and let the investigator make changes

TIME SPENT: With experience, ~ 4 hrs or a half day per application

Evaluation Rubric

TWO CLASSES OF REVIEWER CONCERN

- Setting the wrong stage
- Imbalanced Presentation
- Lack of detail
- Logic gaps
- Important information "hidden"
- Missing requirements

- Significance: right study/right time
- Adequacy of preliminary data
- Appropriateness of techniques, strains/systems, study population, etc.
- Strength and suitability of investigator(s) and environment





Presentation Issue



Example: Evaluation and Diagnosis

Summary Statement Quote: "Moreover, the PI's lab has published extensively on the requirement for [this] signaling pathway in mediating the activation of [certain cells] in response to injury and promoting [organ] regeneration. While this area is controversial, the current proposal is based on largely unpublished data that suggest that activation of [this] signaling is required to activate [a particular] pro-proliferative pathway. This is a very novel finding both for the liver field and for the signaling field."

Insufficient foundation; Going against longstanding ideas

Example: Evaluation and Diagnosis (cont. 1)

Criticism 1. Insufficient foundation

Step 1. Evaluate the Problem

Could be a presentation [imbalanced presentation] and/or scientific issue [need additional data]

Step 2. Collect information needed to diagnose and make a plan

Determine if broader foundation exists and can be presented

→ a couple of supporting papers from other labs had just been published

Step 3. Implement the Solution

Add important new publications that extend evidence beyond the PI's lab

"Our preliminary data in [the tissue of interest] (Figs 4-8) and a single published paper – in a neural stem/progenitor cell line – suggest that [the pathways of interest interact]."

Example: Evaluation and Diagnosis (cont. 2)

Criticism 2. Going against long-standing ideas

Step 1. Evaluate the problem Likely presentation issue [setting the stage]

Step 2. Collect information needed to finalize diagnosis and make a plan Scan early sections of the proposal for language that may be too bold or missing acknowledgements of alternative views

Step 3. Implement the Solution.

Revise to use language that leaves reviewers room for their own biases

"While likely to be controversial, [novel hypothesis proposed]" "Although not widely embraced at first..."

Evaluating Success

Notable Outcomes

- High appreciation out of proportion with the level of effort
- Funded awards! With several showing strong gains moving from "not discussed" to funded

Enables touch on areas we want to impact

- Relevant to all investigators not limiting in scope
- Potential strong benefit to underrepresented minority (URM) faculty who are less likely to resubmit https://diversity.nih.gov/building-evidence/racial-disparities-nih-funding
- Potential to move the bottom line (in a way that feels like support)

Stretching the Rubber Band: Creating innovative approaches that meet research development goals with limited "touch time"



Templates

Martha E. Payne, PhD, RD, MPH



Research Development Associate Office of Research Development Duke University School of Medicine

National Organization of Research Development Professionals Annual Conference 10 May 2017

The Challenge

How do we serve an increasing # of customers with a small office? - Higher touch \rightarrow Lower touch Less hand holding Fewer iterations of review Drafts would come in at last minute Often missing FOA-required elements Other compliance issues

Last Minute Full-Court Press

Extensive edits \rightarrow days, nights & weekends Adherence to FOA instructions Add in required elements Create space for required elements Focus on major compliance issues in addition to final optimization edits Result – <u>high-quality application</u> but also a stressed RD professional

Creation of a Writing Template – Rationale and Preparation

- Increase compliance from start of process
 - Inclusion of required elements
 - Responsive to FOA



- Shift of some RD work to front end
- Thorough review & distillation of requirements
 Funding opportunity
 - Standard instructions (SF424, for NIH)
 - New/revised instructions
 - Other relevant instructions

Creation of a Writing Template – Incorporate Content into Blank Document

- Formatting
- Headings
- General instructions
- FOA-specific instructions
- Other detailed instructions
- Comments

Template Preparation – Review of Funding Opportunity

PAR-15-330 Integrated Preclinical/Clinical AIDS Vaccine Development Program (IPCAVD) (U19)

Overall Component

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

PHS 398 Research Plan (Overall)

The Program Overview of the multi-project application MUST include:

- The scientific question(s) or concepts that are being addressed in the application.
- A Research Design and a Product Development Plan, including timelines that summarize and integrate the activities in the individual projects.
- Documentation of the overall scientific and technical expertise to demonstrate the ability of the team and organization to design, conduct and analyze the proposed studies and developmental activities, including GMP vaccine production, quality assurance oversight; and GLP toxicology studies, if applicable.
- Discussion of how the PD/PI leadership skills, experience and effort proposed will contribute to the management, coordination and leadership of the program. Describe the contributions of the key personnel to the Program as a whole and the integration of those efforts to achieve the goals of the proposed research.
- The plan for clinical development that describes approaches and identifies a clinical trial partner to allow a clinical trial to begin no later than year five of the award. The plan must include a clinical protocol outline including timelines, cost estimates, major milestones, general regulatory strategy, proposed primary clinical endpoints, and statistical considerations.

Template – An Example

Research Strategy - Overall Component Approach section

Clinical protocol outline. Text here.

Proposed primary clinical endpoints. Text here.

General regulatory strategy. Text here.

Statistical considerations. Text here.

Cost estimates. Text here.

Major milestones with measurable go/no-go criteria. Text here.

Timelines. Text here or a Gantt chart.

Comment [MEP25: From the FOA: The Program Overview of the multi-project application MUST include:

 The plan for clinical development that describes approaches and identifies a clinical trial partner to allow a clinical trial to begin no later than year five of the award. The plan must include a clinical protocol outline including timelines, cost estimates, major milestones, general regulatory strategy, proposed primary clinical endpoints, and statistical considerations.

MH notes: Because this Clinical Development Plan describes future activities and is thus different from the other two (not a project per se), more information is required here. Note that the full plan is located in the Admin Core.

Review criteria from the FOA: Is there adequate consideration of requirements to allow a clinical trial to begin no later than year five of the award?

Templates – Policy and Continuing Evolution

From targeted use to policy in 4-6 months
 Service continues to evolve
 Templates developed for additional sections
 Facilities
 Budget justification

Templates – Special Cases

Fleshed-out templates

 e.g., Administrative Core
 Insert content from similar grants
 Add details relevant to team/project
 Information from biosketches

 Combination approach –

 Template + Resubmission review



Templates – Special Case

<u>Combination approach</u> – Template + Resubmission review

1.1. DATA ANALYSIS AND STATISTICAL ISSUES

A full description of the statistical data analysis and sample size considerations is provided in the accompanying **Statistical Analysis Plan** (see **attachment**). A brief summary is provided here:

 Data Analysis for Aim 1: The main focus will be the association of environmental exposures with visual acuity at 6 months and at 3 years. Visual acuity will be treated as a continuous variable as well as a binary variable indicating age-specific subnormal vison. Multivariable regression techniques will be used to account for the influence of other factors such as gestational age that may affect vision and for the impact of developmental delay. In addition, the association of other features with visual acuity will also be investigated.

Comment [MEP1]: <u>Reviewer feedback (Aim 1)</u>: 1. The analysis plan for Aim 1 acknowledges that there is a potential for confounding and that regression models will be used to address the confounding. While this is appropriate at a certain level, it is lacking information on how confounding will be addressed.

Templates – Benefits and Measures of Success

Benefits go beyond writing
 Helps RD professional become familiar with FOA
 Get investigator thinking about certain things early e.g., the need for an External Advisory Board
 Bring in the funder's perspective (with focus on FOA and agency requirements)
 Increased quality of drafts that we receive - much less onerous editing task on back end

Templates – **Benefits and Measures of Success**

High-quality drafts mean Less stress, more satisfaction Happier RD professional High-quality application but with less RD time Happy customers

> "You all were a HUGE help. The template and guidance from the RFA was invaluable." - delighted grant applicant



Templates – Tips and Tricks

- Must be conversant with FOA, instructions, and other relevant guidelines
- Experience helps knowing what should be in a completed grant (esp. for that mechanism)
- Helpful to be familiar with project and team
- Develop templates while team is fleshing out their research ideas



Templates – Conclusion

 Modest amount of time up front saves tremendous amount of time later on
 Quality of finished product comparable to that achieved with our higher touch process of yesteryear but with less RD time

Acknowledgments

Duke University School of Medicine OFFICE OF RESEARCH DEVELOPMENT Joanna Downer, PhD Jennifer Reininga-Craven, PhD Maile Henson, PhD

PRIOR GRANT APPLICANTS

Questions?



martha.payne@duke.edu

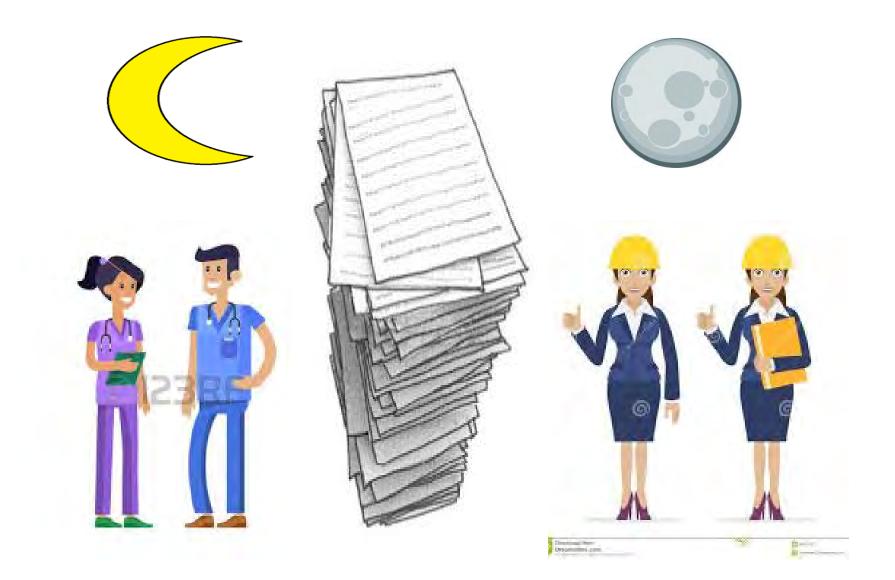


S-t-r-e-t-c-h-i-n-g the rubber band: creating innovative approaches that meet research development goals with limited "touch time"

> Anda Cytroen Director, Research Development School of Engineering

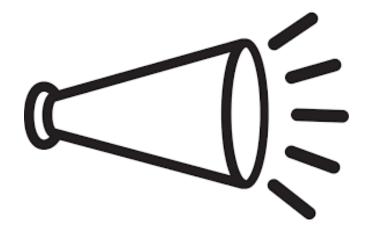
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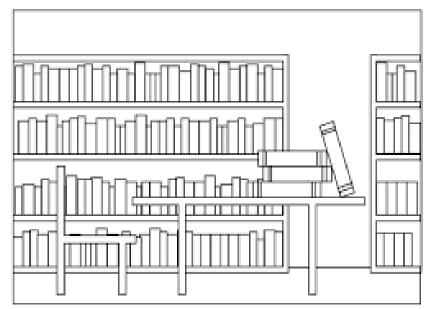
School of Engineering



RUTGERS

School of Engineering





www.theleanningsite.info



Solution: the "SOE Research" kiosk/library

- ✓ Uses an already available University intranet platform
- ✓ Familiar to faculty as a course management tool
- ✓ Free
- ✓ Secure

RUTGERS

School of Engineering

This is what the welcome page looks like:

	CAREER Award workshops 🗸					
OE Research 🗦	і ≡номе					
«	SITE INFORMATION DISPLAY	RECENT ANNOUNCEMENTS				
A ter access View	PEDIT % LINK 7 HELP	% LINK ? HELP				
i≣ Home	Welcome!	OPTIONS				
€ nouncements	We hope that this is a useful resource for you to get announcements and to make relevant resources available to you.	Announcements				
Resources	At the left, "Announcements" holds all the news and information disseminated to site participants.	(viewing announcements from the last 10 days)				
Mailtool	Also at the left is "Resources" where you will find two folders:	OARC: NSCI webinar: "Supercomputers and Superintelligence", Tuesday, 5/9 1-3PM				
esst professor aculty bios	"I need information on"	(Anda Cytroen - May 1, 2017 3:30 pm)				
0	and	DARPA Discover DSO Day: June 15, 2017 @ (Anda Cytroen - Apr 28, 2017 3:57 pm)				
oE assistant ulty bios and posters	"I would like to learn more about"	Lewis Burke: on campus May 24: 1:1 meetings available and a presentation: An overview of how the Department of Defense funds science and technology (Anda Cytroen - Apr 24, 2017 11:37 am)				
C Statistics	Please feel free to search and explore. If there is material that you would like to add or change, please let me know (anda.cytroen@rutgers.edu).					
Site Info	Thank you!					
0		(C				

RUTGERS

Announcements cover broad areas of interest to PIs, grad and undergraduate students, staff. These are curated from weekly funder feeds, funding opportunity subscriptions, internal and external smaller, unique funding opportunities.

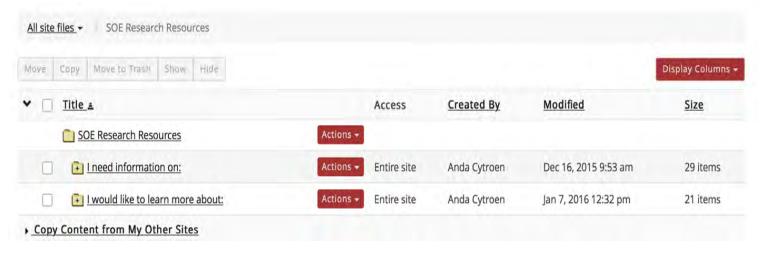
Announcements also include policy changes (e.g. NIH stipend information) and internal post-award guidance:

A access View	Announcements (viewing announcements from the last 365 days)								
III Home									
	View All								
esources	Viewing 1 - 10 of 594 items								
Mailtool	< < show 10 items ▼ > >								
Site Info East professor faculty bios SoE assistant culty bios and posters thelp	Subject	Saved By	Modified Date	For	Beginning Date	Ending Date	Remove?		
	Lewis Burke: Defense Policy Newsletter (March 2017)	Anda Cytroen	Mar 2, 2017 7:51 am	site					
	N interesting read: why reproducibility matters: a lesson from Rutgers colleagues	Anda Cytroen	Feb 28, 2017 11:08 am	site					
	C Edit								
	ORED: information regarding SBIR/STTR funding	Anda Cytroen	Feb 27, 2017 5:43 pm	site			0		
	⊗ ORED: technology service request If Edit	Anda Cytroen	Feb 27, 2017 1:25 pm	site					

Resources includes two sections:

"<u>I need information on</u>": templates, instructions, suggested language, examples and information in common use on proposal submissions

"I would like to learn more about": informational tools and articles on career development, mentoring, approaching funders with proposal ideas, broader topics



"I need information on": is designed to be a quick resource:

	Actio	
	Carl I need information on:	Actio
	A guide to SOE proposal development and submission	Actio
	F Bibliographies	Actio
	F Big Ten Alliance	Actio
	F Biosketches	Actio
	Budgets and budget justifications	Actio
	Data management plans	Actio
	DOE (US Department of Energy)	Actio
	Evaluation plans	Actio
	Funding opportunities (including PIVOT information)	Actio
	GA salary and tuition	Actio
	Gift or Grant?: information and resources	Actio
	GrantForward (ORED's funding opportunity search tool)	Actio
	• Management plans	Actio
	主 Multiple PI plan	Actio

RUTGERS

For example, the "budgets and budget justifications" folder includes:

Budgets and budget justifications	
lank DOD budget page (ARO99).xls	
Blank NIH personnel Justification.docx	
Jank NSF budget individual sheet.doc	
blank NSF budget page with instructions.doc	
Word Joint More Blank NSF budget year 1.docx	
DARPA general budget format abc 2016.xlsx	
eneric budget justification.docx 🕕	
NIH postdoctoral stipend levels FY2017 (use for calculating GA costs on NIH grant budgets)	
Notice regarding postdoc salary minimums September 30, 2016 Office of Research.pdf	
ONR YIP budget template by task and govt FY.xlsx	
OOS Tuition reimbursement policy March 2016.pdf	

RUTGERS

The "I would like to learn more about" file includes topics about career development, communicating science, articles by topic – less emergent, but of interest:

🔄 I would like to learn more about:
Career management
Communications
<u>core facilities</u>
DARPA (Defense Advanced Research Projects Agency)
Endnote
Finding funding
Graduate student education
Human subjects research
Indirect costs (aka F&A)
Intellectual Property
interesting reads
Mentoring
► ORAU
🕞 proiect management



<u>Approach</u>

- Started to build it after first 2 years
- Goal was to keep it simple or else it would not be used
- Kept it offline until built and piloted with some faculty and staff
- Populated it with developed templates and links



Lessons learned:

Listen: be mindful about what's really needed and what will be useful over time in planning: be aware of local customs

Distill: don't push information for information's sake

Tweak: as needed: pay attention to use and to comments and quantifiable metrics to demonstrate value and inform improvements and keep content fresh

Some unexpected benefits/outcomes:

- Target was School faculty and staff, but central grants office and other staff now utilize and provide content to the library and announcements (e.g. Office of Corporate Engagement)
- Use of tracking statistics was a built-in feature that was not activated at the outset, but now is being monitored and will be used to demonstrate value:

OVERVIEW R	REPORTS PREFERENCES						
Overview							
	2552	89	148	72 son.	72 son.		
Show more	Visits	Users who have visited sit	e Site Members	Members who have visited site	Members who have not visited site		
Activity	292	Resources and C	ytroean.				
Enumer more	Events		Most active user				
Resources	388	26 SOE a	sst profess	. ed451			
Show more	Files		st opened file	User who has opened the	nost files		



Thank you!





Early Career Fellowship Support Shut Up and Write

Caroline Ang University of Bath





- 1. Fellowship support programme
- 2. Shut-Up and Write

Early Career Fellowship Support





Marie Skłodowska-Curie Actions Individual Fellowships (MSCA IFs)

Main priorities:

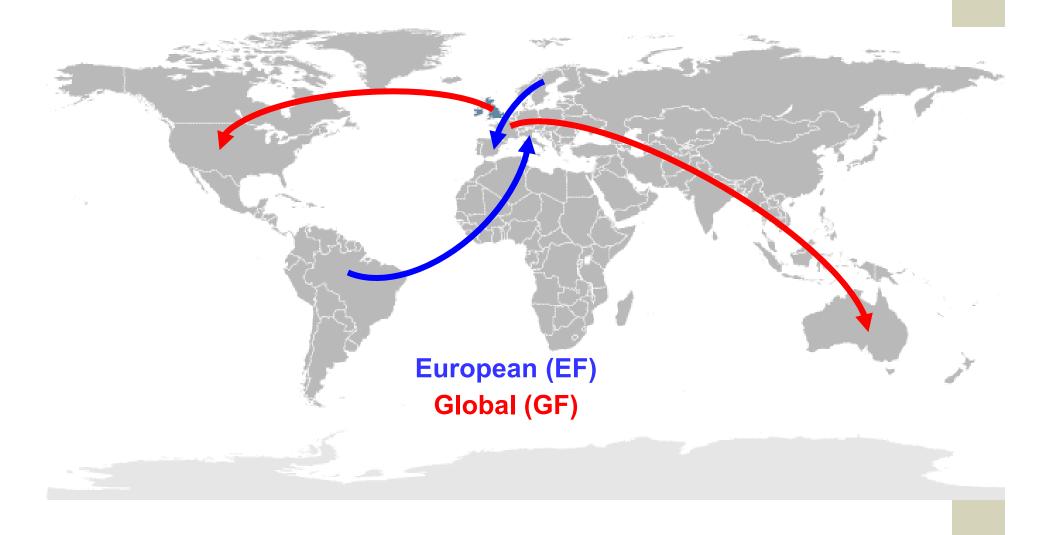
- Career development
- International & intersectoral mobility
- Transfer of knowledge and skills
- Strengthen networks both academic and non-academic

Annual total budget of ~€250M Aimed at postdoc level and higher 12-24 month duration Each fellowship worth up to ~€200K



Types of Fellowships





Why Support MSCA IFs?



- Prestigious
- Attracts excellent researchers from all over the world
- Generous level of funding to researchers and institution
- High number of submissions (in excess of 20/yr for Bath)



MSCA IF Challenges



- Applicants based abroad
- Fellowship value is below what Research Development team would normally engage with
- Supporting individual applicants is time-consuming as it involves:
 - Internal review (25-page long proposals!)
 - Answering (endless) queries
 - Maintaining internal deadlines

Support We Provide



- 1. Proposal template "cheat sheet"
- 2. Information podcasts
- 3. Internal review

Cheat Sheet



- Detailed written guidance for each proposal section based on guide for applicants and previously successful proposals
- Introduced for 2013 call

However...

- Still answering a lot of (the same) questions
- Not sure applicants read the guidance very carefully
- Some issues difficult to communicate with the cheat sheet

What more can we do?







- Short videos (no more than 5min each) focusing on the main sections
- Applicants can access externally and watch at their leisure
- Two colleagues developed the script and slides
- Recorded using in-house lecture capture infrastructure
- To be rolled out for 2017 call (September deadline)

https://goo.gl/rWu5iM

MSCA IF Internal Review



2013

Two rounds of internal review exclusively from two Research Development Managers (too much work!)

2014-2015

First review between applicant and Bath host, second review by 1-2 Research Development managers (still a lot of work!)

2016-present

Second review by panel of 4-6 Pre-Award Development Officers – reduces burden on each reviewer, new skill training for our development officers

Preparation & Evaluation



Cheat sheet – 5 days

Podcasts – 2 weeks

Proposal development process – begins 4-5 months before deadline, 2-3 weeks total work including review

- Bath's success rate ranges from 15-20% (average success rate ~15%)
- Applicants and hosts are very positive about support

Shut Up and Write (SUAW)





- Originated by writers in San Francisco to support their community, held in local cafés
- Researchers tell us that a main barrier to writing proposals is finding protected time and a quiet space
- Could we adapt this idea for campus?



Started July 2015
First Monday of every month, 10am-1pm
Drop-in
Coffee/tea and snacks available
1-2 Research Development Managers on hand to answer questions, provide advice

Name controversy! Coffee machine controversy!

What Works Best



- Regular time, easy to reach regular venue with somewhere nearby to go for conversations
- One month prior to first session advertised with flyers posted around campus
- Bought coffee machine
- Now publicise with reminder emails and tweets 1-2 weeks prior to session, advertise at all our workshops and info sessions
- All supplies (coffee machine, coffee, tea, cups, snacks) fit in small box and tote bag

Evaluation and Preparation



- Average number of people attending 5-6 per session
- Both new and repeat participants from most disciplines
- Range from early career to senior faculty
- Unsolicited comments very positive
- Often leads to further follow-up and meetings
- Will survey annually to track submissions

Very easy to prepare & run:

- A few emails & tweets
- Three hour session
- 15min set-up/clean-up
- Time and cost of buying refreshments

Writing Retreat – SUAW on steroids



Run every six months (July 2016 & Jan 2017)

Two-days off-campus

Attendees intend to submit grants of at least £250k within six months

Full range of professional services staff on hand, including:

- Research development
- Pre-award (finance)
- Communications
- Public engagement
- Researcher development
- Commercialisation
- Library (research analytics)
- Alumni & Development

More time to write

More support

More researchers: 15-20/retreat More expensive! £3,500/event Currently evaluating





Please feel free to email me with any questions or comments:

Caroline Ang

c.w.ang@bath.ac.uk

Panel Conclusions & Advice

- Notice when services that took little time & effort routinely receive big praise or are frequently requested and think about expanding access [resubmission review; templates; intranet]
- When expanding or broadening a service area, consider specific settings where your unique perspective and/or skill set can have a big impact with minimal time and effort [resubmission review; templates]
- If you're engaging in a task repeatedly or if you represent a process bottleneck, consider creating a resource [intranet; fellowship toolkit]
- If you see recurrent problems, the solution may be to develop a preventative strategy [templates; fellowship toolkit]
- Take a step back to look at what you're doing and analyze why; see if you can identify a pattern you're following or a framework for dissemination and training in that service [templates + timeline combination; resubmission review]