



Simplifying the Proposal Process

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Clinical Trial?

Industry Sponsored Clinical Trials

Clinical Trial – Research Process Manager (CT-RPM)

**Federal Grant sponsored Clinical Trials will follow the grant process*

Focus is on Grant Proposals

- **Funding Opportunity Listserv** (Email [Chelsey Perry](mailto:Chelsey.Perry) to join)
▪ <http://med.stanford.edu/rmg/funding.html>
- Stanford **Research Development Office** is now open to assist in the preparation of grants for **large multidisciplinary projects** and to help **early-career assistant professors** write grants.

Planning for your submission - Timeline

- Notification to RMG via Proposal Intake Form (PIF)
 - › 1 month (30 days) prior to sponsors deadline
- Subcontracts?
 - › Notification to RMG via PIF 1.5 months (45 days min.) prior to sponsors deadline

Step 1 – Proposal Notification

Proposal Intake
Form (PIF)

**PIF = all “external” funding*

***Stanford Internal funding (seed grants) = No PIF/ No RMG involvement*

SeRA System

- Standardizes the **proposal initiation process**:
 - Grants
 - Subcontracts
 - Sponsored research agreements
- Standardizes **key information**:
 - Program announcement, etc.
- Initiates the **budgeting process**
- Captures **PI approval & Conflict of Interest**

<http://med.stanford.edu/rmg/grants/proposal-preparation---submission/proposal-intake-form--pif-.html>

Step 2 – Are Waivers Needed?

Proposal Intake
Form (PIF)



Waivers?

Waivers = when contradicts established policy

1. **Effort** Waivers (1% SOM PI Effort)
2. **Who's Eligible to be a Principal Investigator?**

Research Policy Handbook 2.14 establishes the policy that **PIship** and **Co-PIship** on sponsored projects is limited to members of the:

- Academic Council
- Medical Center Line (MCL) Faculty

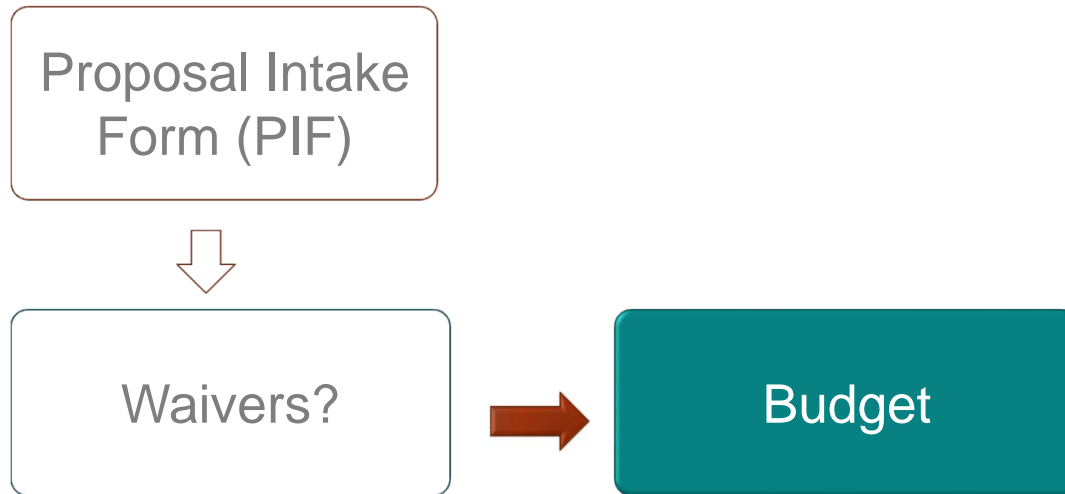
3. **PI Waivers** needed for:

- Postdoctoral Scholars
- Resident/ Clinicians
- Academic Staff members
- Instructors

<http://med.stanford.edu/rmg/grants/proposal-preparation---submission/pi-eligibility---waivers.html>

Stanford University

Step 3 - Budget



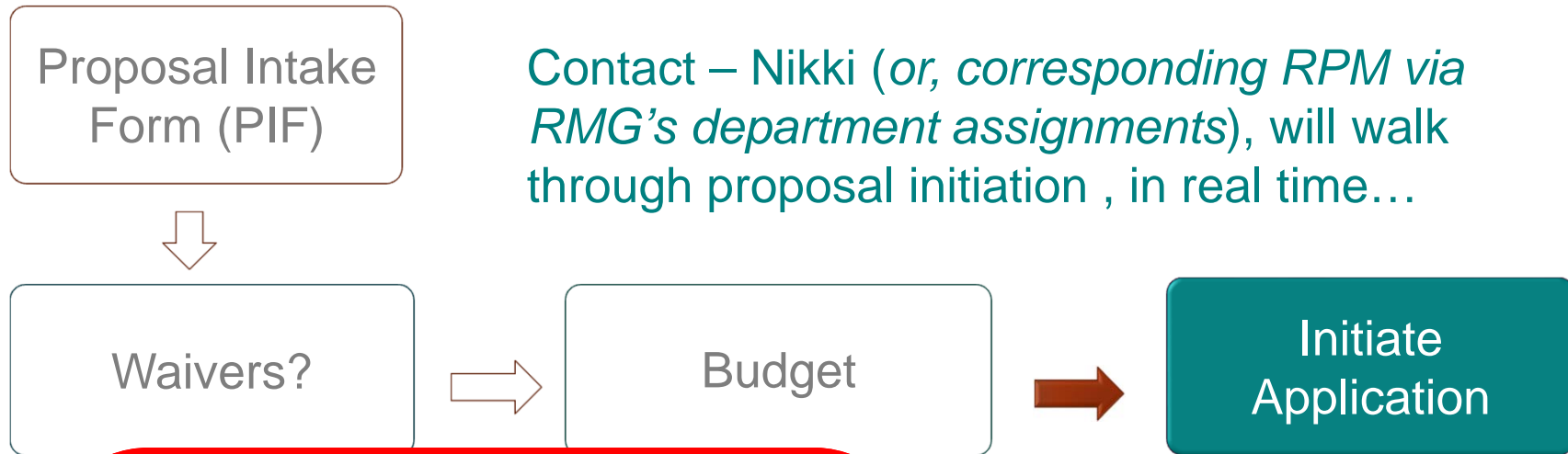
Budget **allocation** & **allowable cost categories** are specified by the announcement/ solicitation.

- Federal?
 - (i.e., Full IDC/ Typically budget “direct” costs + IDC)
- Non-federal?
 - (i.e., IDC varies, when IDC is zero – 8% ISC charged to PI’s unrestricted account).
- Industry Contract?
 - (i.e., Full IDC/ Typically negotiate “total” costs)

If are including **subcontracts** – recommended to specify allocation to them.

<http://med.stanford.edu/rmg/grants/proposal-preparation---submission/budget-development.html>

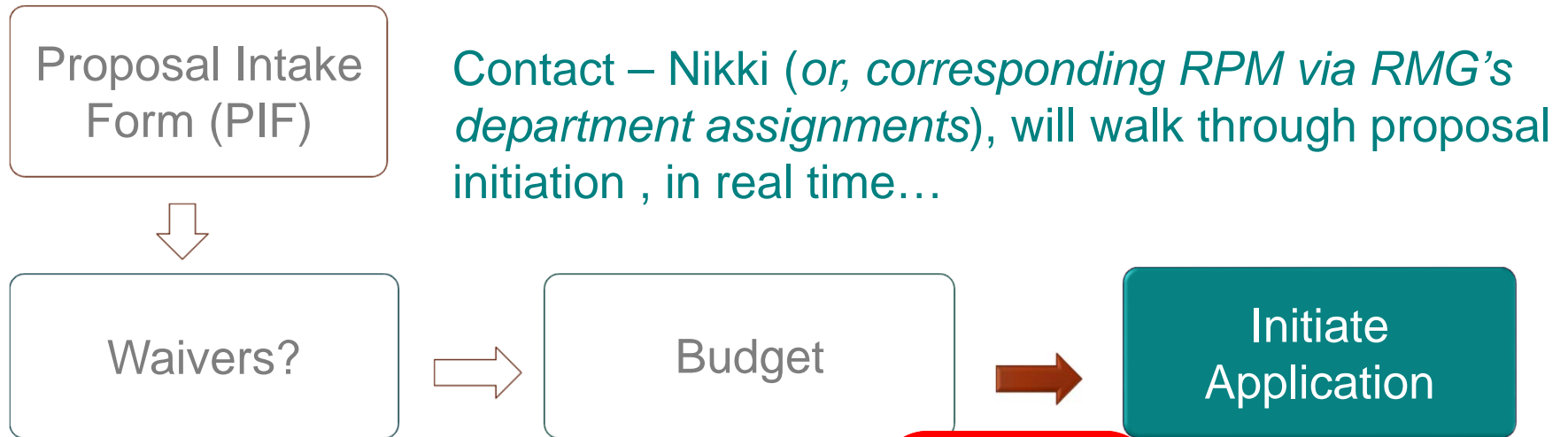
Step 4 – Initiate Application



Contact – Nikki (or, corresponding RPM via RMG’s department assignments), will walk through proposal initiation , in real time...

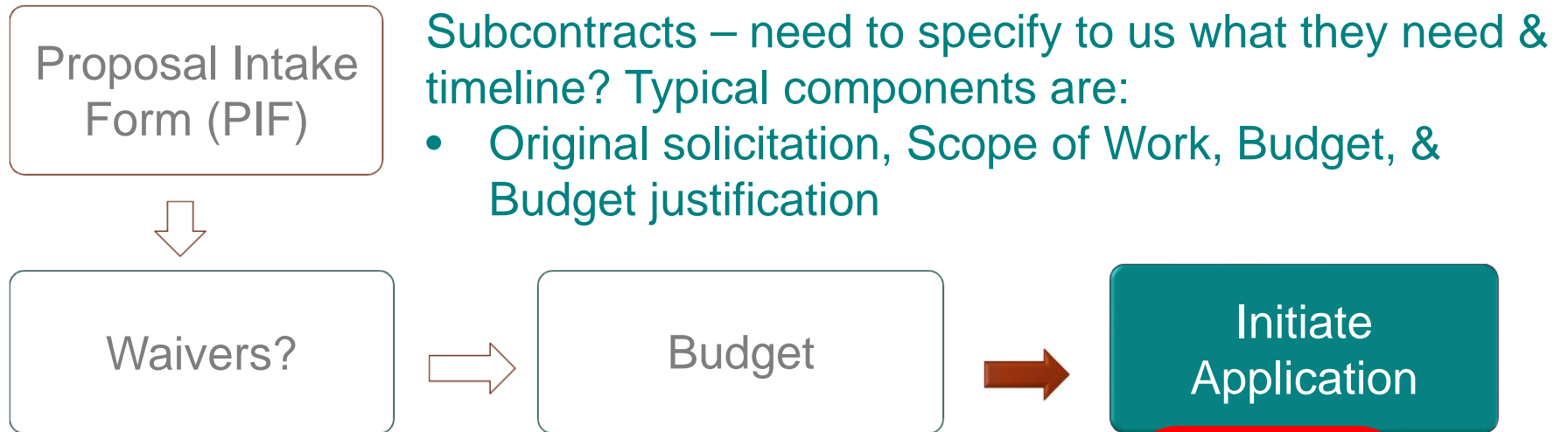
Fed	Fed	Fed	Non-Fed	Fed / Non-Fed
NIH	NSF	DOD	Foundation	Subcontract
ASSIST	FastLane	eBRAP (LOI)	Proposal Central	Email
		Cayuse (Application)	↓	
		eBRAP (Verify)	“Stanford University”	

Step 4 – Initiate Application



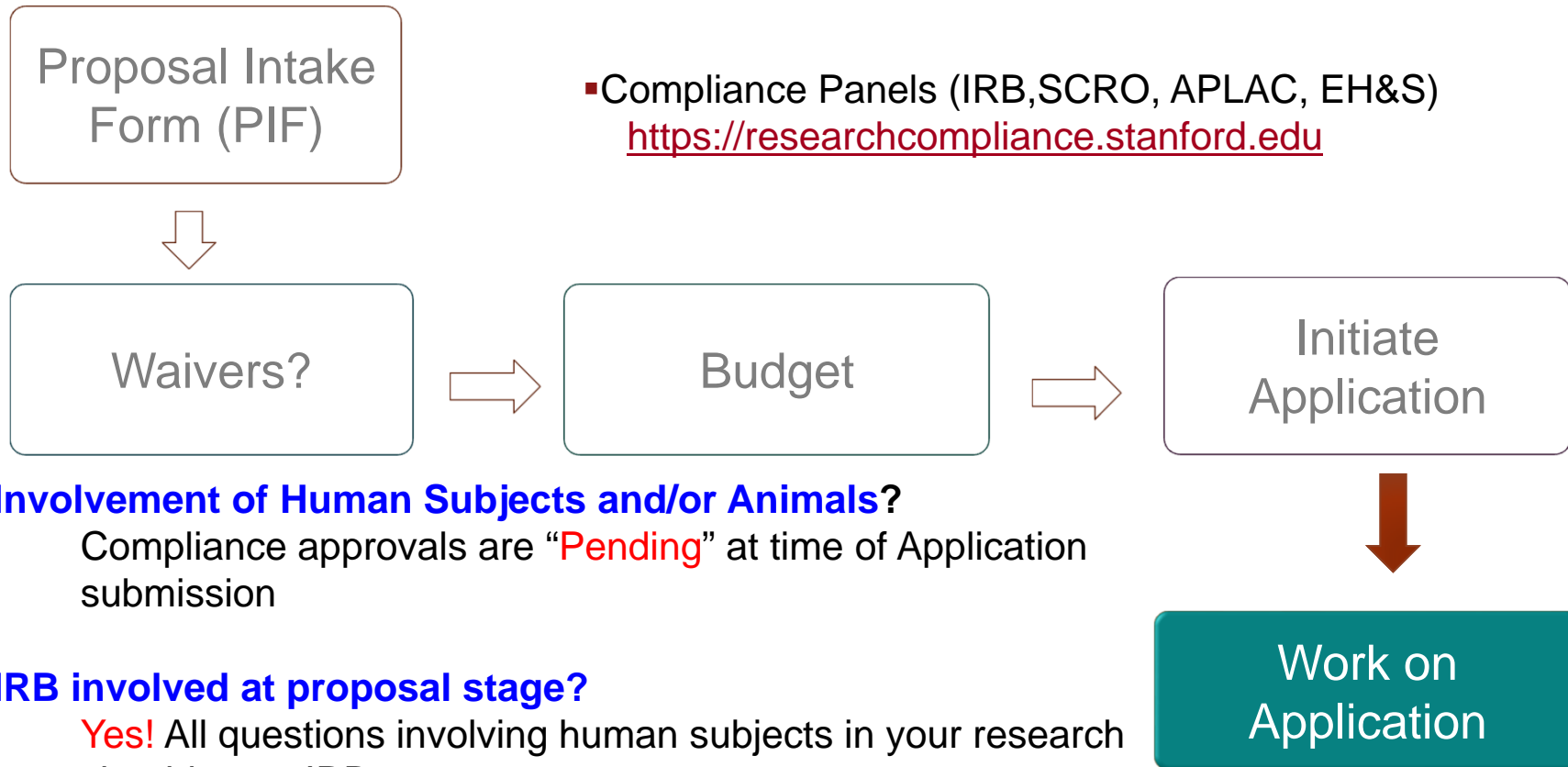
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*No Appendix!		eBRAP (Verify)	“Stanford University”	

Step 4 – Initiate Application



Fed	Fed	Fed	Non-Fed	Fed / Non-Fed
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Step 5 – Work on Application



Involvement of Human Subjects and/or Animals?

Compliance approvals are “**Pending**” at time of Application submission

IRB involved at proposal stage?

Yes! All questions involving human subjects in your research should go to IRB.

De-identified data?

Submit a human subjects determination to IRB – IRB will then provide concurrence

<http://med.stanford.edu/rmg/grants/proposal-preparation---submission/proposal-components--carousel-internal-menu.html>

NIH R01 PROPOSAL CHECKLIST

PI Name
SPO#:
Sponsor: National Institutes of Health (NIH)
Mechanism Type Parent R01 (No - clinical trial)
RFA # PA-19-056
URL https://grants.nih.gov/grants/guide/pa-files/pa-19-056.html#_Section *Scroll to Section IV. Application and Submission Information
<https://grants.nih.gov/grants/how-to-apply-application-guide/forms> *Scroll to Research Instructions (PDF)
<https://grants.nih.gov/grants/how-to-apply-application-guide/forma> *Page Limits
***Links to key information!**

Proposal Documents (Attachments in PDF Format)	Page Limits	Responsibility	Due Dates
BUSINESS & SCIENCE (<i>minus Research Strategy and Bibliography/References Cited</i>)			ALL Documents Due
BUDGET & BUDGET JUSTIFICATION			
Detailed Budget (non-modular)	Use R & R budget forms	PI and RPM	
Budget Justification (Detailed budget)	No limit	PI and RPM	
OTHER PROJECT INFORMATION			
Project Summary/Abstract	maximum 30 lines total *Scroll to pg 40	PI	
Project Narrative	2 to 3 sentences *Scroll to pg 40 of NIH	PI	
*Bibliography and References (see bottom of table)	No limit *Scroll to pg 40 of NIH Research	PI	
Facilities and Other Resources	No limit *Scroll to pg 41 of NIH Research	PI	
**Equipment (if applicable)	No limit *Scroll to pg 42 of NIH Research	PI	
SENIOR / KEY PERSON			
Biosketches for Key Persons	5 page limit per person *Scroll to pg 50	PI	
HUMAN SUBJECTS			
PHS Human Subjects and Clinical Trials Information	No limit *Starts on pg 94 of NIH Resear	PI	
2.4 Inclusion of Women, Minorities, and Children	No limit *Starts on pg 109 of NIH Resear	PI	
2.5 Recruitment and Retention Plan	No limit *Starts on pg 111 of NIH Resear	PI	
2.7 Study Timeline	No limit *Starts on pg 112 of NIH Resear	PI	
Inclusion Enrollment Report (add data table via NIH function)	No limit *Starts on pg 112 of NIH Resear	PI	
3.1 Protection of Human Subjects	No limit *Starts on pg 117 of NIH Resear	PI	
RESEARCH PLAN			
Specific Aims	1 page limit *Scroll to pg 81 of NIH Res	PI	
*Research Strategy (see bottom of table)	12 page limit *Scroll to pg 81 of NIH Re	PI	
**Vertebrate Animals (if applicable)	No limit *Scroll to pg 87 of NIH Researc	PI	
**Select Agent Research (if applicable)	If applicable; No limit *Scroll to pg 88 o	PI	
**Multiple PD/PI Leadership Plan (Required - if 2 or more PIs)	If applicable; No limit *Scroll to pg 89 o	PI	
**Consortium/ Contractual Agreements (Required - if have subs	If applicable; No limit *Scroll to pg 89 o	PI	
**Letters of Support (if applicable)	As needed *Scroll to pg 90of NIH Rese	PI	
Resource Sharing Plan	No limit *Starts on pg 90 of NIH Resear	PI	
**Authentication of Key Biological and/or Chemical Resources	If applicable; 1 page suggested *Scroll	PI	
**PHS Assignment Request	Optional *Scroll to pgs 131 of NIH Research Instructions PD		
***Appendix - NO Attachments!!! Check with Nikki before uploading anything here! Applications are being rejected due to non-conforming "Appendix attachments"			
SCIENCE (<i>Research Strategy & Bibliography/ References cited</i>)			5 Business Days before Submission Deadline
OTHER PROJECT INFORMATION			
*Bibliography and References	No limit *Scroll to pg 40 of NIH Researc	PI	
RESEARCH PLAN			3 Business Days before Submission Deadline
*Research Strategy	12 page limit *Scroll to pg 81 of NIH Re	PI	

SPONSOR DEADLINE

NOTES:

¹ All science must be submitted in PDF format
Label attachments to correspond to upload (i.e., Budget Justification, Project Abstract, Project Narrative, Facilities and Other Resources, etc. etc.)
 NIH can now accept project titles up to 200 characters (with spaces)
NO headers, footers, or page numbers for all documents

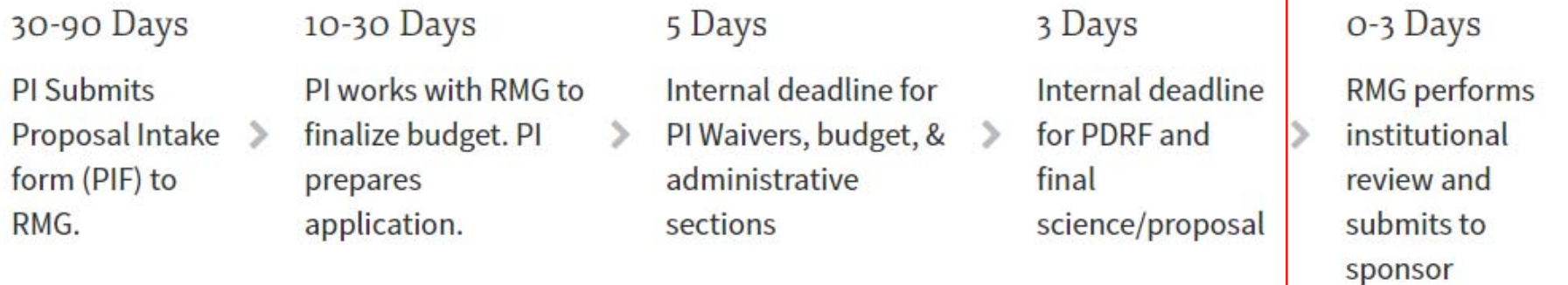
SUBCONTRACT NOTES:

Subcontracts: Please connect me ASAP to Grants Contact at your collaboration site.
** for projects where you plan to issue a subcontract, please submit your proposal intake form (PIF) 1.5 months in advance (documents and approvals are needed from that institution; and, most institutions have a 2-week mandatory timeline for review, before returning to us).*
Subcontracts: PIs will discuss budget limitations with the subcontract PIs.
Subcontractor INDIRECT COSTS should not be included when determining if the budget exceeds the total direct cost limit

Steps 6-7, Review, Feedback, Submit

Proposal Preparation & Submission Timeline

Actions Prior to Due Date



Review & Feedback



Submission!

Questions?

