

# Using Feasibility Reviews to Avoid Common Research Pitfalls

Clinical Research Support Center (CRSC)

# Agenda

- Who are we ?
- What is feasibility review ?
- Why assess feasibility ?
- How your project will be assessed ?
- How to request this service ?

# Who are we?

## CLINICAL RESEARCH SUPPORT CENTER

The CRSC is a collaborative group of **experts**, co-located in the Bio - Medical Library to provide a new, **cross - functional**, team - based approach to **guide** and **support** clinical **researchers** and study teams.

***\*\*The CRSC is here to help make connections to all cross - functional experts.\*\****

### CRSC Team :

- Clinical Trials Financial Services (CTFS)
- Research Navigator
- **Research Preparation Group (RPG)**
- Regulatory Specialists
- Best Practices Integrated Informatics Core (BPIC)
- Biostatistical Design & Analysis Center (BDAC)
- Community Engagement to Advance Research & Community Health (CEARCH)
- Fairview Research Administration
- HRPP - Institutional Review Board (IRB)
- HRPP - IND/IDE Regulatory
- Oncore
- REDCap
- Sponsored Projects Administration (SPA)

*Permanently located in CRSC*

*Office Hours in CRSC*

*Available by referral/Ad hoc : OTC, BLS, ODAT, UMP and others*

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**CRSC is a collaboration among:**

Clinical and Translational Science Institute; Office of the Vice President for Research; Fairview Health Services; University of Minnesota Physicians

# Who Are We?



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*Clinical Research  
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**Nicole Tosun**  
*Clinical Research  
Specialist*

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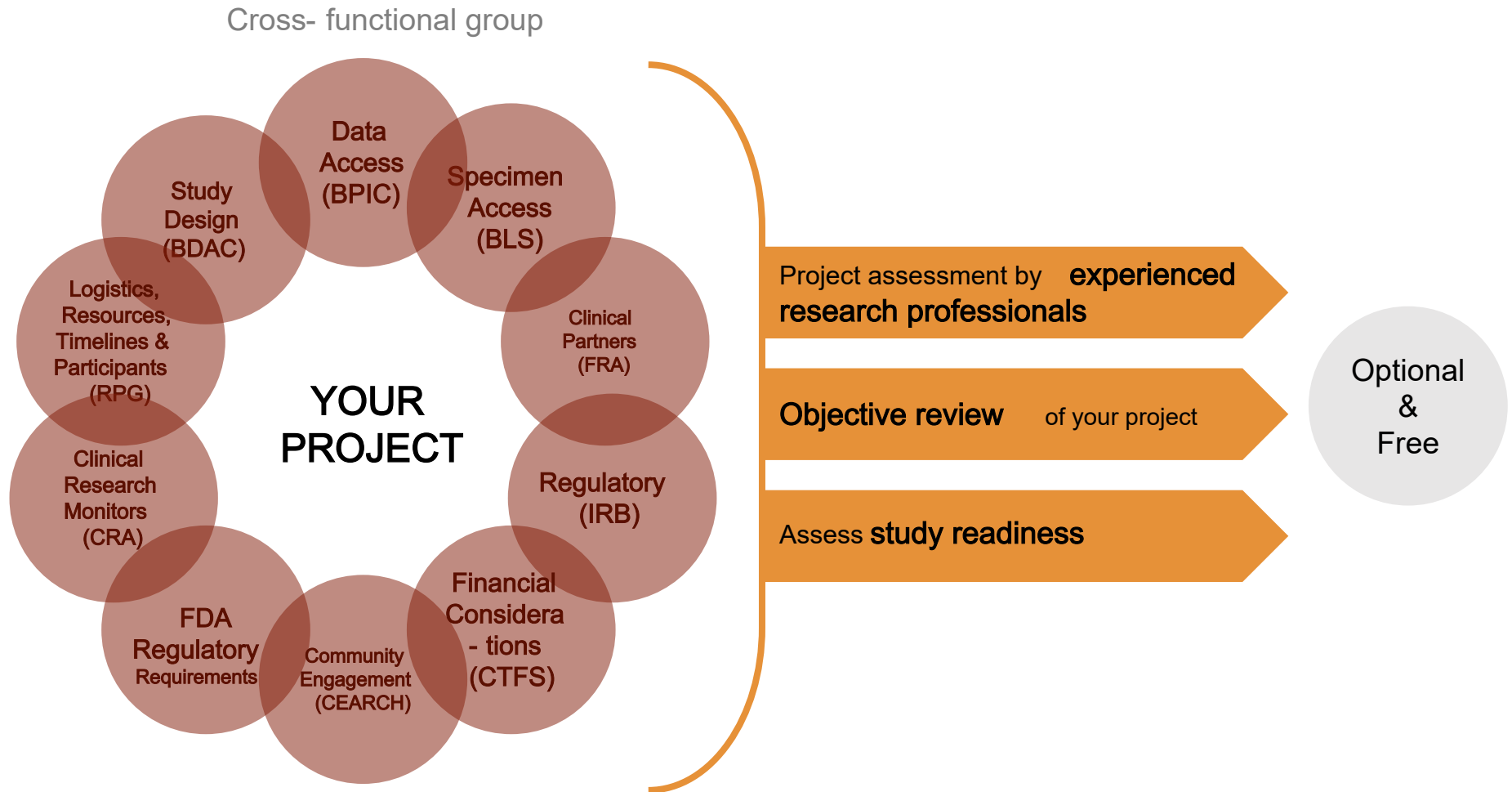
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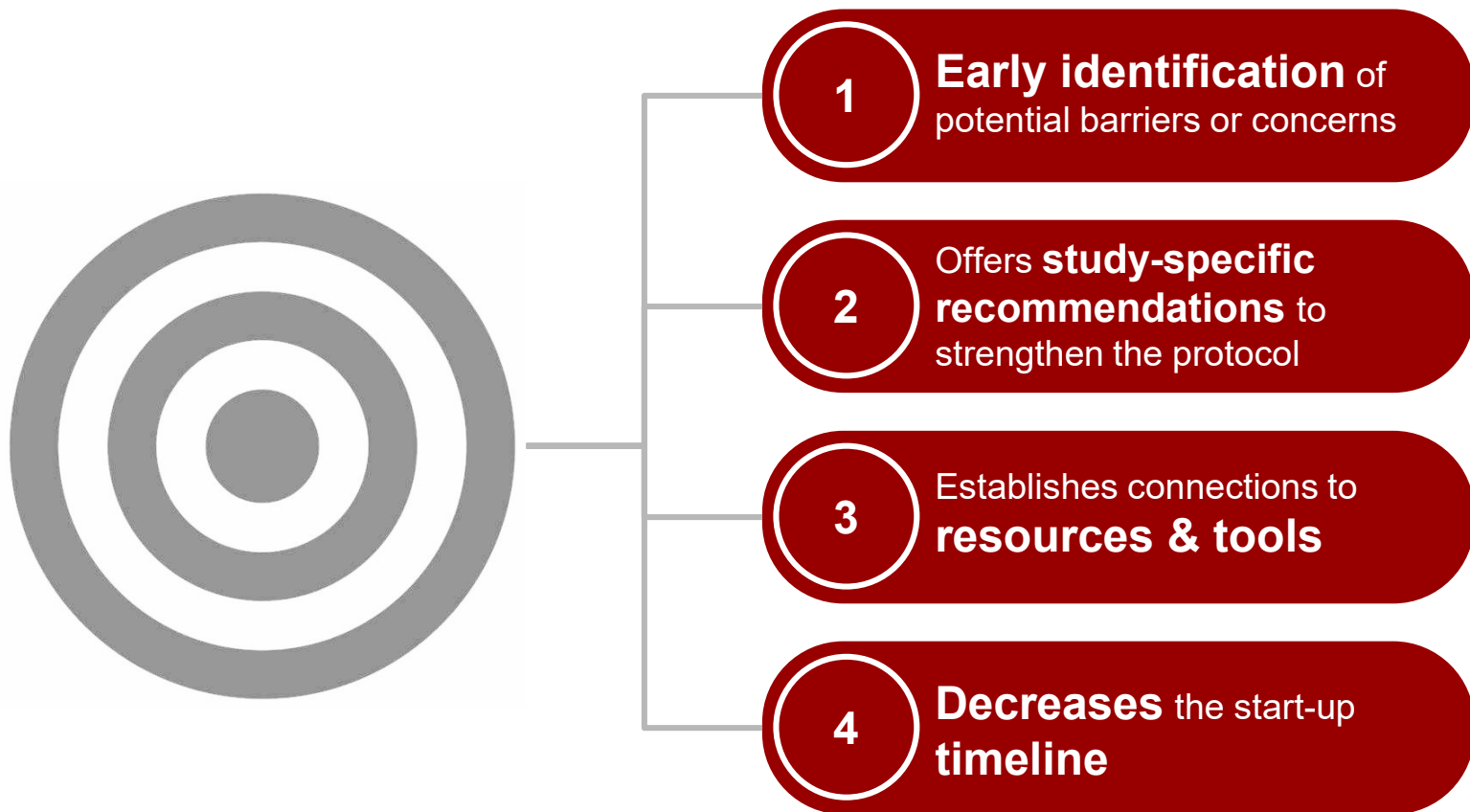
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# What is feasibility review?



# Why assess feasibility?



⇒ To help you and your team work through the start - up process more quickly  
from IRB to First Participant Enrolled

# How your project will be assessed?

*1 Week Turnaround*



- Documents reviewed:
  - Complete study protocol (final draft/ready for IRB submission)
    - If B&I study, site supplement to sponsor protocol
  - Consent forms
  - Study budget (if available)



# How your project will be assessed?

*1 Week Turnaround*

Protocol sent to  
cross-functional  
experts

Experts review  
and assess for  
concerns &  
suggestions

Review meeting  
held with experts  
and PI/study team

Research Prep  
Group provides  
written summary  
to study team

- Structured and objective review

Protocol Section	Section Title	Cross-Functional Review Group	Feasibility Review Question	No Concerns Minor Concern(s) Major Concern(s) Not enough info Not Applicable	Explanation	Suggestions & Resources
1.0	Objectives					
1.1	Purpose	BDAC	Are the specific aims well formulated?			
		BDAC	Is the overall study design appropriate to address the specific aims?			
		FDA Regulatory	Does the trial require clinicaltrials.gov registration? Are all of the following statements true? -Does the study involve human participants? -Are participants assigned to an intervention? -Is the study designed to evaluate the effect of the intervention on the participants? -Is the effect being evaluated as health-related biomedical or behavioral outcome? If yes to all, then the study is required to be registered.			
2.0	Background					
2.1	Significance of Research Question/Purpose	CEARCH	Does this research involve health issues or concerns that disproportionately impact underserved communities? If so, have researchers planned to include and engage members of those communities in the study plan and/or dissemination plan?			
		CEARCH	Are other stakeholders being consulted or included in study planning and implementation?			
		CEARCH	Do researchers have existing relationships with stakeholders or community organizations? Are plans in place to develop these relationships if not?			



# How your project will be assessed?

*1 Week Turnaround*

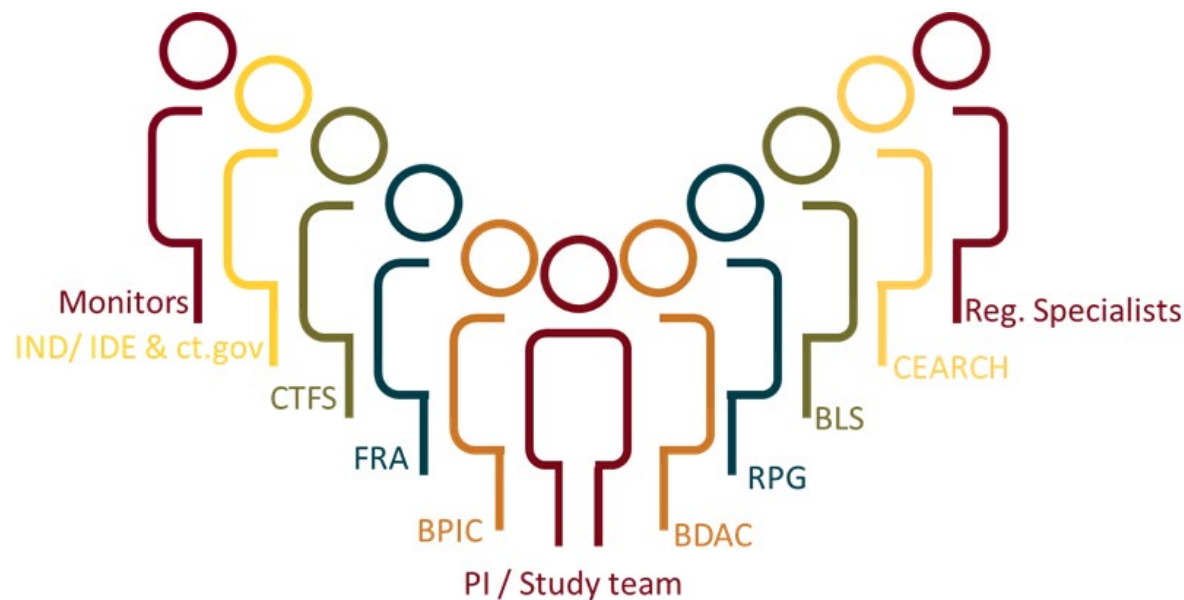
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- Thursdays Review Meetings



Session 1: 12 - 1:30 pm

Session 2: 1:30 - 3 pm

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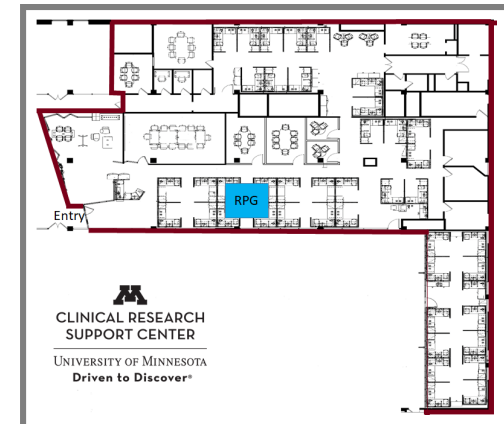
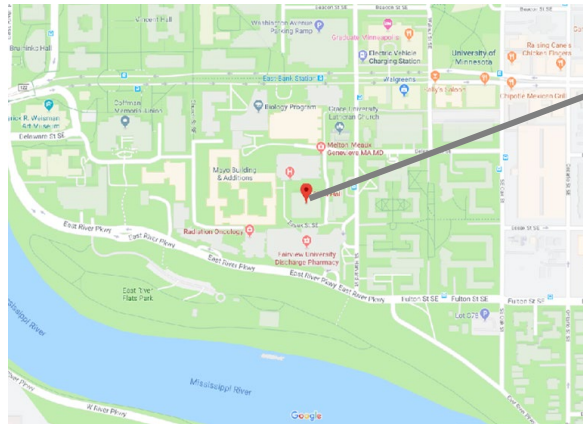
Research Prep  
Group provides  
written summary  
to study team

- Written Summary for PIs & Study Team
  - Cross- functional expert contact information
  - Areas of strength
  - Areas of consideration & suggestions
  - Action items/resources



# How to request this service?

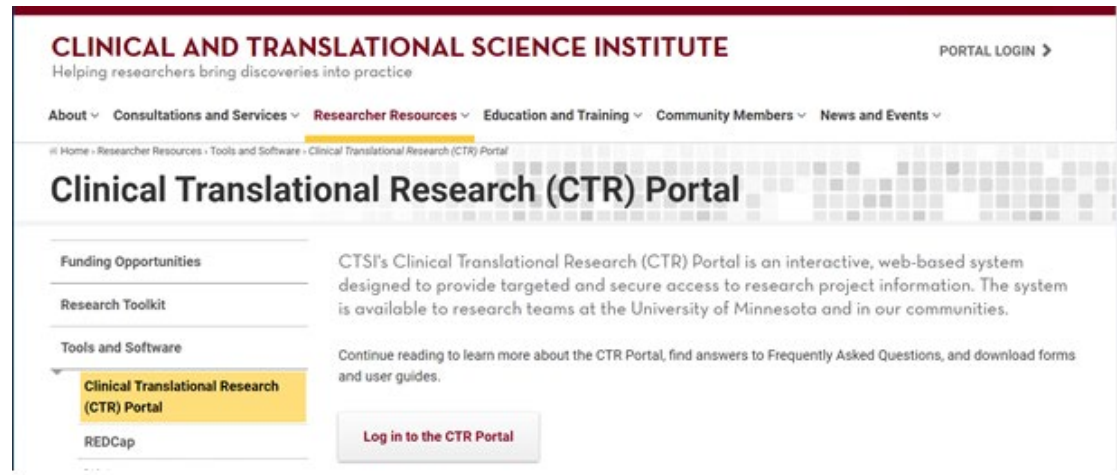
- 1 Email Us: Francoise Mercadier - Crevel [fmercadi@umn.edu](mailto:fmercadi@umn.edu)
- 2 Call: RPG Team Line: 612 - 624 - 4929
- 3 Visit us at the CRSC:



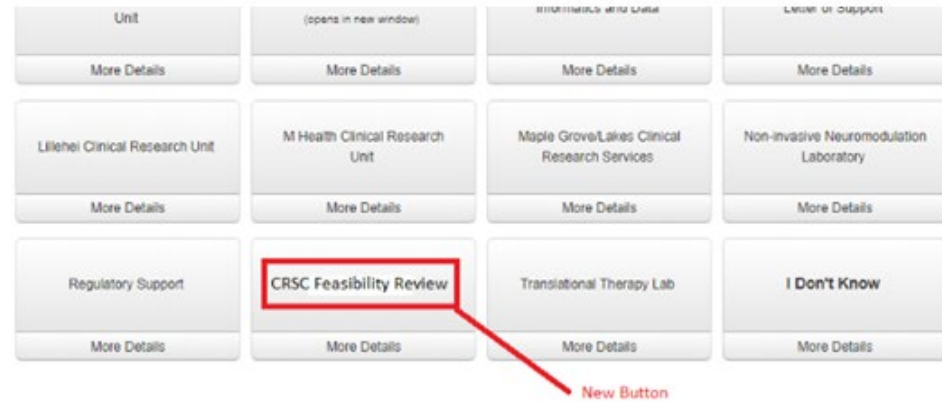
# How to request this service?

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## CTR Portal :



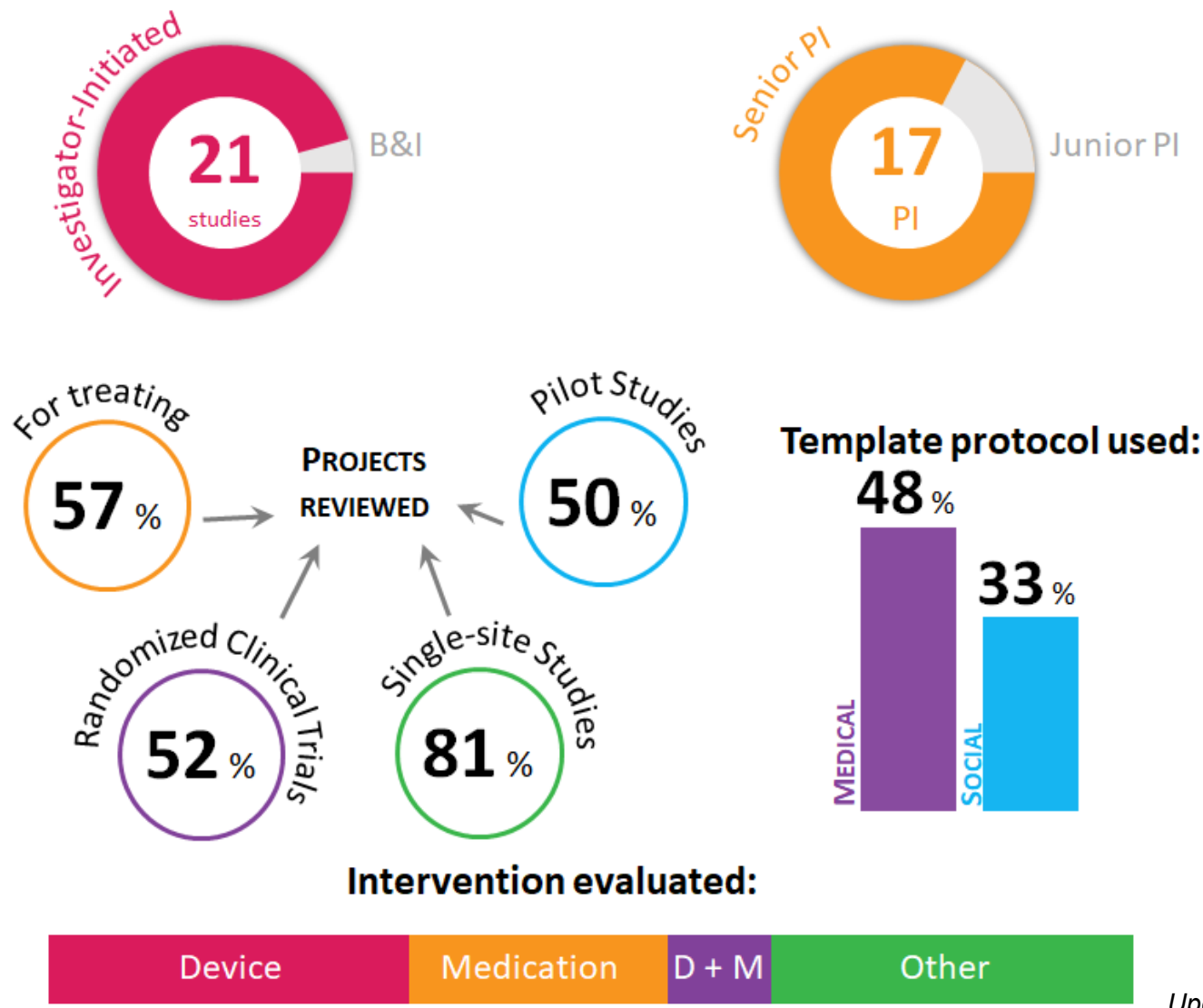
Select  
CRSC Feasibility Review



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# Feasibility reviews by Numbers



Updated: 07-Dec-2018

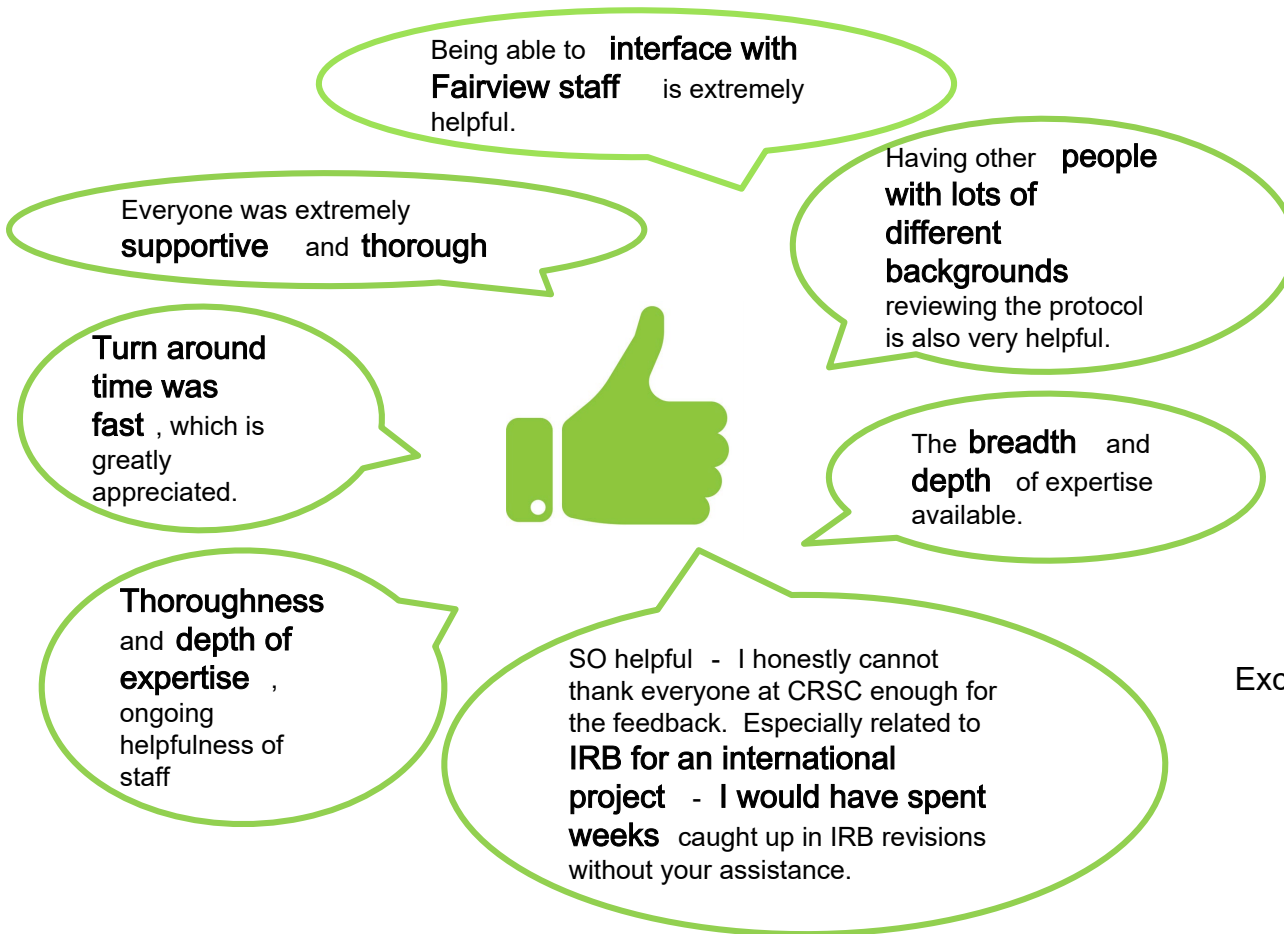


# Continuous Improvement Initiatives

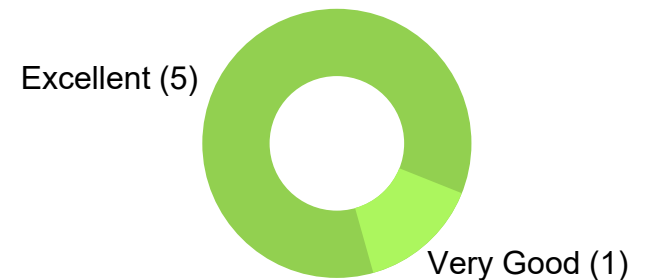
- New CRSC ancillary review in ETHOS which allows the RPG team to view study progress
- Revised feasibility review assessment template to improve usability, transparency and impact.
- REDCap survey to seek feedback from PI/Study team members

# Feedback from surveys

What did you like about the feasibility review process?



Overall experience with the CRSC feasibility review process:

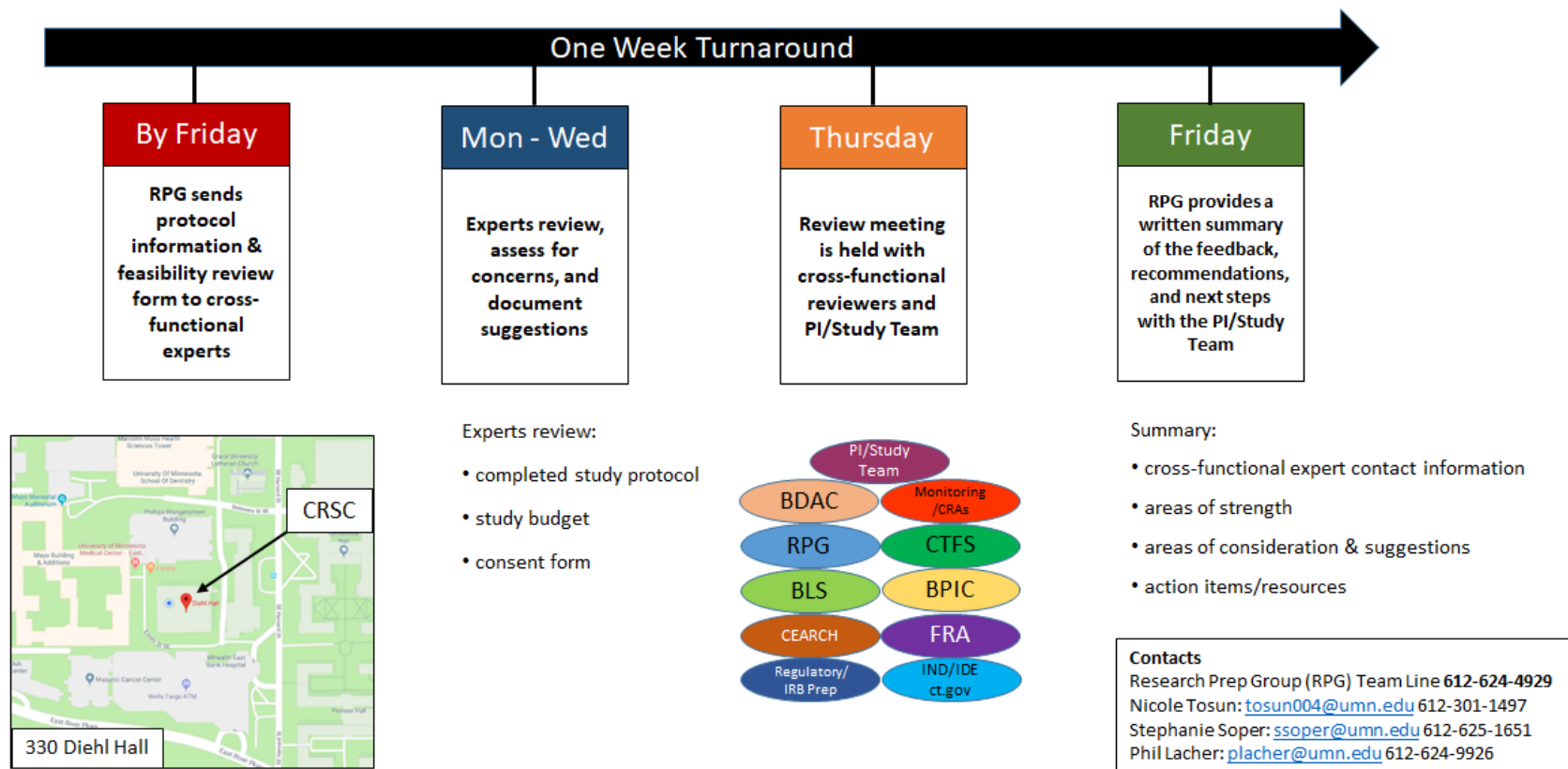






# Questions?

# CRSC Feasibility Review



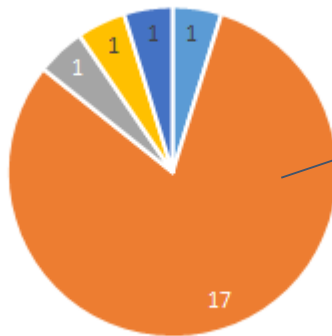
## Goal

*To help investigators & study teams work through the start-up process more quickly through IRB to first participant enrolled*

# Metrics

21 studies reviewed to - date

Affiliation of Principal Investigator



■ College of Science and Engineering ■ Medical ■ Medicine ■ Nursing ■ Social Work

Psychiatry (4)  
Dermatology (3)  
Medicine (3)  
Pediatrics (2)  
Obstetrics, Gynecology and  
Women's Health (1)  
Pediatrics (1)  
Family Medicine and Community  
Health (1)  
Surgery (1)  
Rehabilitation Medicine (1)