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 Biomedical 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
Who Are We?

**RESEARCH P REP GROUP**

**Francoise Mercadier - Crevel**
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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
What is feasibility review?

Objective review of your project
Assess study readiness

YOUR PROJECT

Cross-functional group

- Study Design (BDAC)
- Logistics, Resources, Timelines & Participants (RPG)
- Clinical Research Monitors (CRA)
- FDA Regulatory Requirements
- Community Engagement (CEARCH)
- Financial Considerations (CTFS)
- Clinical Partners (FRA)
- Regulatory (IRB)
- Specimen Access (BLS)
- Data Access (BPIC)

Project assessment by experienced research professionals
Optional & Free

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University of Minnesota

Driven to Discover®
Why assess feasibility?

1. Early identification of potential barriers or concerns
2. Offers study-specific recommendations to strengthen the protocol
3. Establishes connections to resources & tools
4. Decreases the start-up timeline

⇒ 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

● Structured and objective review

<table>
<thead>
<tr>
<th>Protocol Section</th>
<th>Section Title</th>
<th>Cross-Functional Review Group</th>
<th>Feasibility Review Question</th>
<th>Explanation</th>
<th>Suggestions &amp; Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Objectives</td>
<td>BDAC</td>
<td>Are the specific aims well formulated?</td>
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<td></td>
<td></td>
<td>BDAC</td>
<td>Is the overall study design appropriate to address the specific aims?</td>
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<tr>
<td>1.1</td>
<td>Purpose</td>
<td>FDA Regulatory</td>
<td>Does the trial require clinical trial registration? Are all of the following statements true?</td>
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<td>- Does the study involve human participants?</td>
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<td>- Are participants assigned to an intervention?</td>
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<td>- Is the study designed to evaluate the effect of the intervention on the participants?</td>
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<td>- Is the effect being evaluated as health-related biomedical or behavioral outcome? If yes to all, is the study required to be registered?</td>
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<tr>
<td>2.0</td>
<td>Background</td>
<td>CERCH</td>
<td>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?</td>
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<tr>
<td>2.1</td>
<td>Significance of Research Question/Purpose</td>
<td>CERCH</td>
<td>Are other stakeholders being consulted or included in study planning and implementation?</td>
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<td></td>
<td>CERCH</td>
<td>Do researchers have existing relationships with stakeholders or community organizations? Are plans in place to develop these relationships if not?</td>
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</tbody>
</table>
How your project will be assessed?

1 Week Turnaround

- Thursday Review Meetings

Session 1: 12 - 1:30 pm
Session 2: 1:30 - 3 pm
How your project will be assessed?

1 Week Turnaround

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

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
How to request this service?

1. Email Us:  Francoise Mercadier - Crevel  fmercadi@umn.edu

2. Call:  RPG Team Line: 612 - 624 - 4929

3. Visit us at the CRSC:
How to request this service?

4 CTR Portal:

Select CRSC Feasibility Review
Feasibility reviews by Numbers

- Investigator-Initiated: 21 studies
- Senior PI: 17 PI

For treating:
- Randomized Clinical Trials: 52%
- Single-site Studies: 81%
- Pilot Studies: 50%

Template protocol used:
- Medical: 48%
- Social: 33%

Intervention evaluated:

<table>
<thead>
<tr>
<th>Device</th>
<th>Medication</th>
<th>D + M</th>
<th>Other</th>
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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?

- Being able to interface with Fairview staff is extremely helpful.
- Everyone was extremely supportive and thorough.
- Turn around time was fast, which is greatly appreciated.
- Thoroughness and depth of expertise, ongoing helpfulness of staff.
- Having other people with lots of different backgrounds reviewing the protocol is also very helpful.
- The breadth and depth of expertise available.
- SO helpful - I honestly cannot thank everyone at CRSC enough for the feedback. Especially related to IRB for an international project - I would have spent weeks caught up in IRB revisions without your assistance.

Overall experience with the CRSC feasibility review process:

- Excellent (5)
- Very Good (1)
Questions?
CRSC Feasibility Review

One Week Turnaround

By Friday
RPG sends protocol information & feasibility review form to cross-functional experts

Mon - Wed
Experts review, assess for concerns, and document suggestions

Thursday
Review meeting is held with cross-functional reviewers and PI/Study Team

Friday
RPG provides a written summary of the feedback, recommendations, and next steps with the PI/Study Team

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

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Contacts
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Stephanie Soper: ssoper@umn.edu 612-625-1651
Phil Lacher: placher@umn.edu 612-624-9926
21 studies reviewed to date

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)