Why does it have to be so difficult?
How a Feasibility Review can help advance the study start up process and set investigators up for success
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Background
Starting a research study at an academic institution can be complex. Challenges range from poor study design to low enrollment, homogeneity of the sample and limited resources. In a competitive research environment, it is critical to get a study off the ground quickly with a well-designed protocol.

Purpose
The University of Minnesota’s Clinical Research Support Center (UMN CRSC) designed and implemented a Feasibility Review process that helps investigators efficiently get their protocol approved while increasing the chance of success in execution.

Methods
One week review process
Documents reviewed:
- Protocol
- Consent forms
- Budget
- Recruitment materials

Reviewers will:
- Flag areas of concern that may lead to IRB stipulations
- Provide guidance and specific language for the protocol

A meeting is held:
- With experts, investigator(s) and study team
- Provide feedback and discuss solutions

Summary includes:
- Areas of strength and consideration
- Specific language
- Action items & resources
- Expert contact info

Results
Types of Studies
- Randomized Controlled Trial: 38%
- Cohort Study: 5%
- Before & After: 9%
- Cross-sectional: 9%
- Case Series: 18%
- Case Control: 21%

Protocol-Related IRB Stipulations
- Less than 1 for 55%
- Between 0 and 1 for 35%
- Between 2 and 3 for 10%
- Greater than 3: 0

Investigator Feedback
- Average Satisfaction Score: 4.8 out of 5.0
- 96% of investigators plan to follow recommendations

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Conclusions
- Key Takeaway: The UMN CRSC Feasibility Review results in a robust, polished protocol that is ready for IRB submission and successful execution.
- Next Steps: We will continue evaluating how this support service is reducing start-up timelines and helping investigators meet enrollment goals.