



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

CLINICAL RESEARCH SUPPORT CENTER

UNIVERSITY OF MINNESOTA
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Purpose

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:

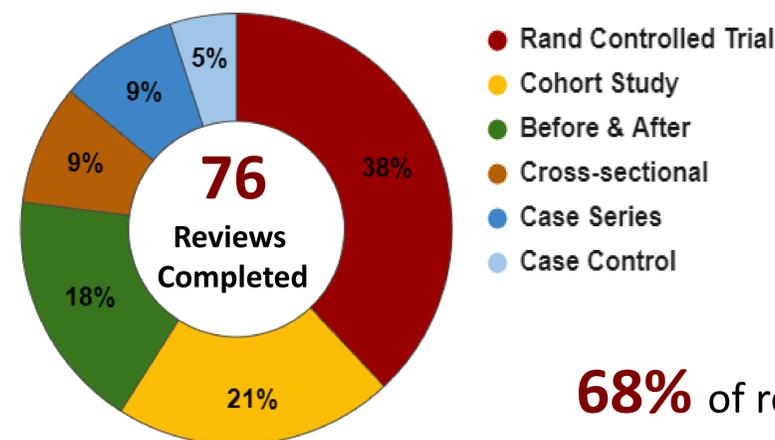
- With experts, investigator(s) and study team
- Provide feedback and discuss solutions

Summary includes:

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

Results

Types of Studies



Investigator initiated studies



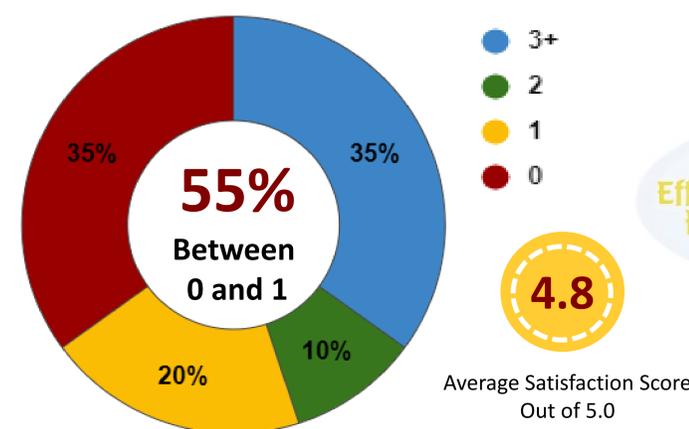
Includes an investigational drug or device



Testing therapeutic treatments

68% of reviews were for experienced researchers

Protocol-Related IRB Stipulations



Investigator Feedback



96% of investigators plan to follow recommendations

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.

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