ePCT Essentials Worksheet: Considerations As You Plan Your Project

Resources at: rethinkingclinicaltrials.org

Aims & Significance

What decisions is the trial intended to inform?

In what setting?

Who are the stakeholders?

What are the key research questions/specific aims?

Participants

Who is eligible to participate (eg, should anyone be excluded for safety reasons)?

How will they be identified?

Design

Will the trial employ cluster-randomized or stepped-wedge design?

What will be the unit of randomization (eg, individual patient, provider, clinic)?

Sample Size

If cluster-randomized, what is the estimate of intracluster correlation coefficient?

Intervention

What kind of expertise (operational, clinical) is needed to deliver the intervention?

Will there be flexibility in how intervention is delivered?

What degree of adherence flexibility will be tolerated?

Outcomes

How will outcomes be ascertained (eg, passive or active data collection)?

What is their relevance to stakeholders?

Human Subjects Protection

Who are the participants and how should they be protected?

Is written informed consent required of any participants?

Analysis

What will be the unit of analysis (eg, individual patient, provider, clinic)?

Are all observations included (ie, intent-to-treat)?

Pilot and Feasibility Testing

What elements are essential to pilot before conducting the trial?

Dissemination, Implementation, Sustainability

How does my partner healthcare system learn?

What aspects of my trial address effectiveness?

What aspects address sustainable implementation?

How will I manage unanticipated changes in my trial?