

## ePCT Essentials Worksheet: Considerations As You Plan Your Project

Resources at: [rethinkingclinicaltrials.org](http://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?

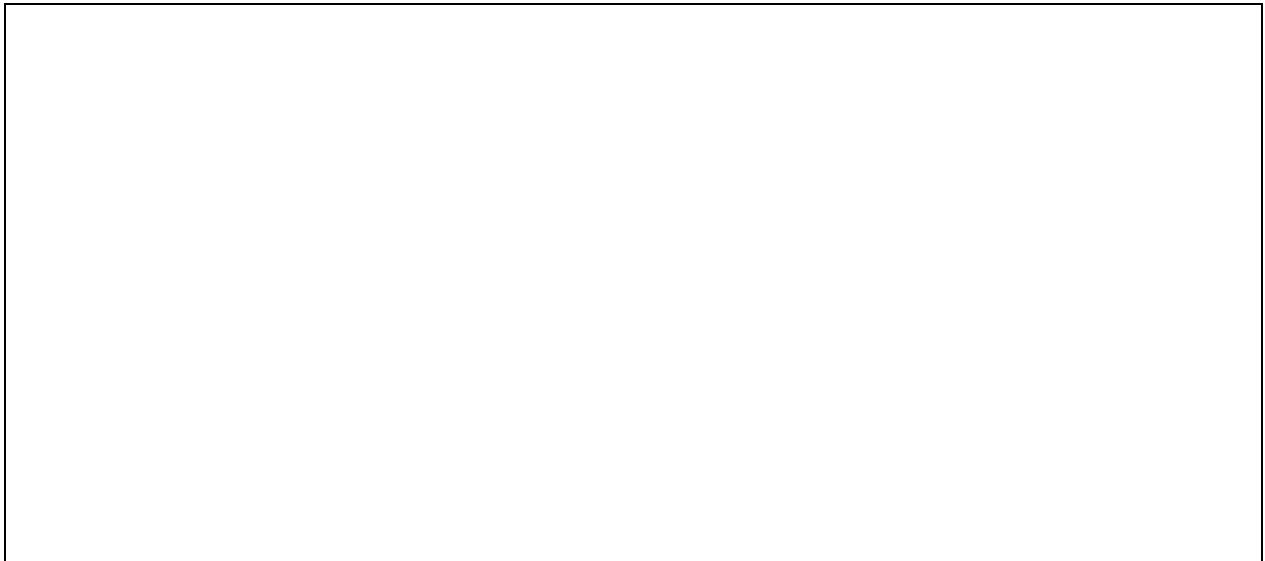
**Analysis**

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?

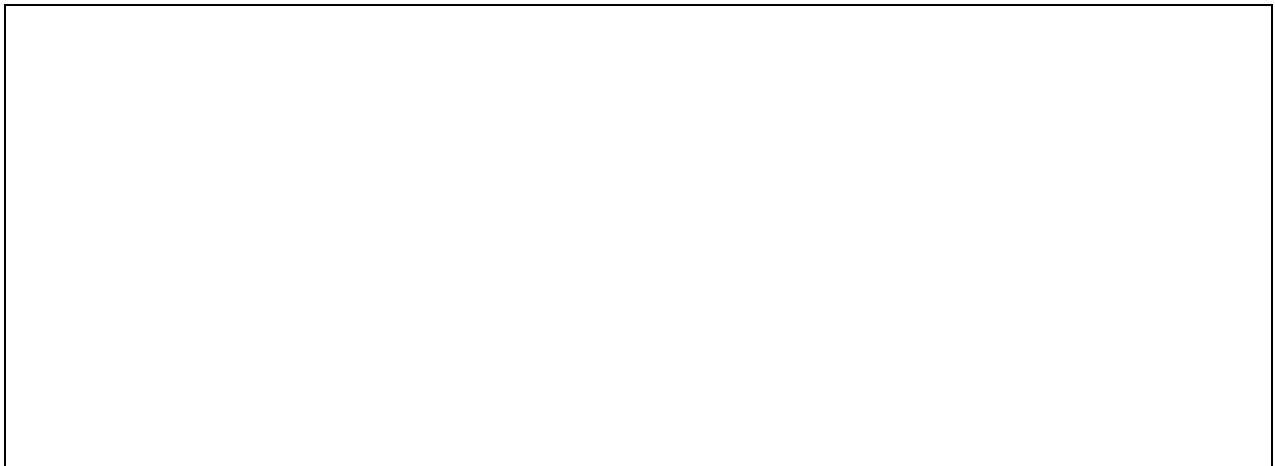


### **Dissemination, Implementation, Sustainability**

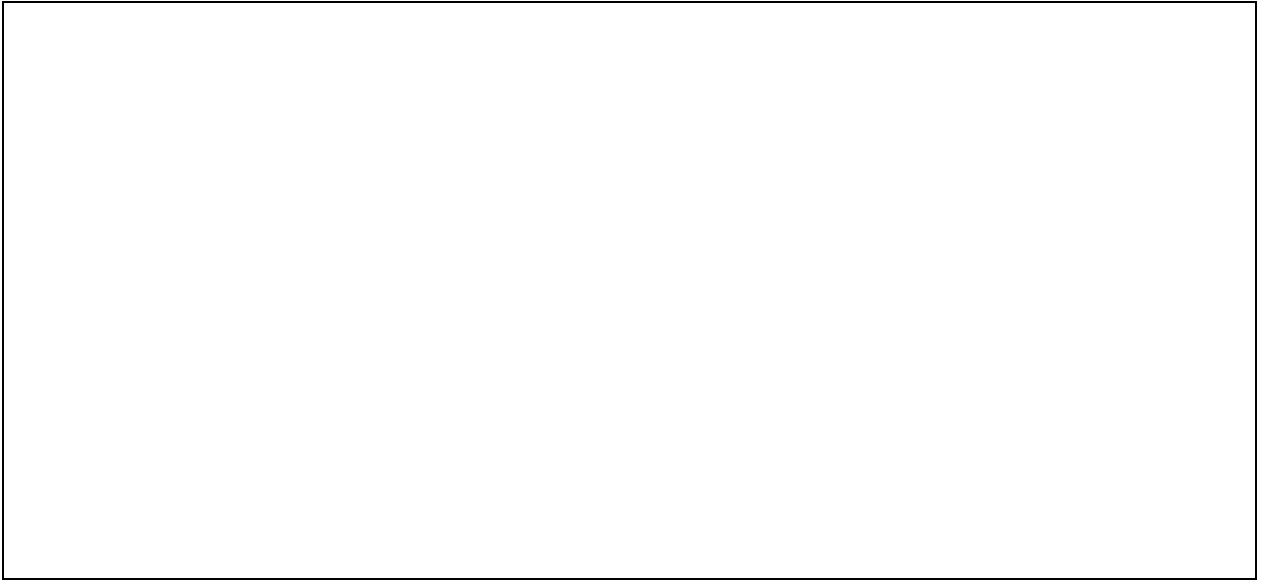
How does my partner healthcare system learn?

What aspects of my trial address effectiveness?

What aspects address sustainable implementation?



**How will I manage unanticipated changes in my trial?**

A large, empty rectangular box with a thin black border, intended for the user to provide a written response to the question above.