

Worksheet: Next Steps for Your Project

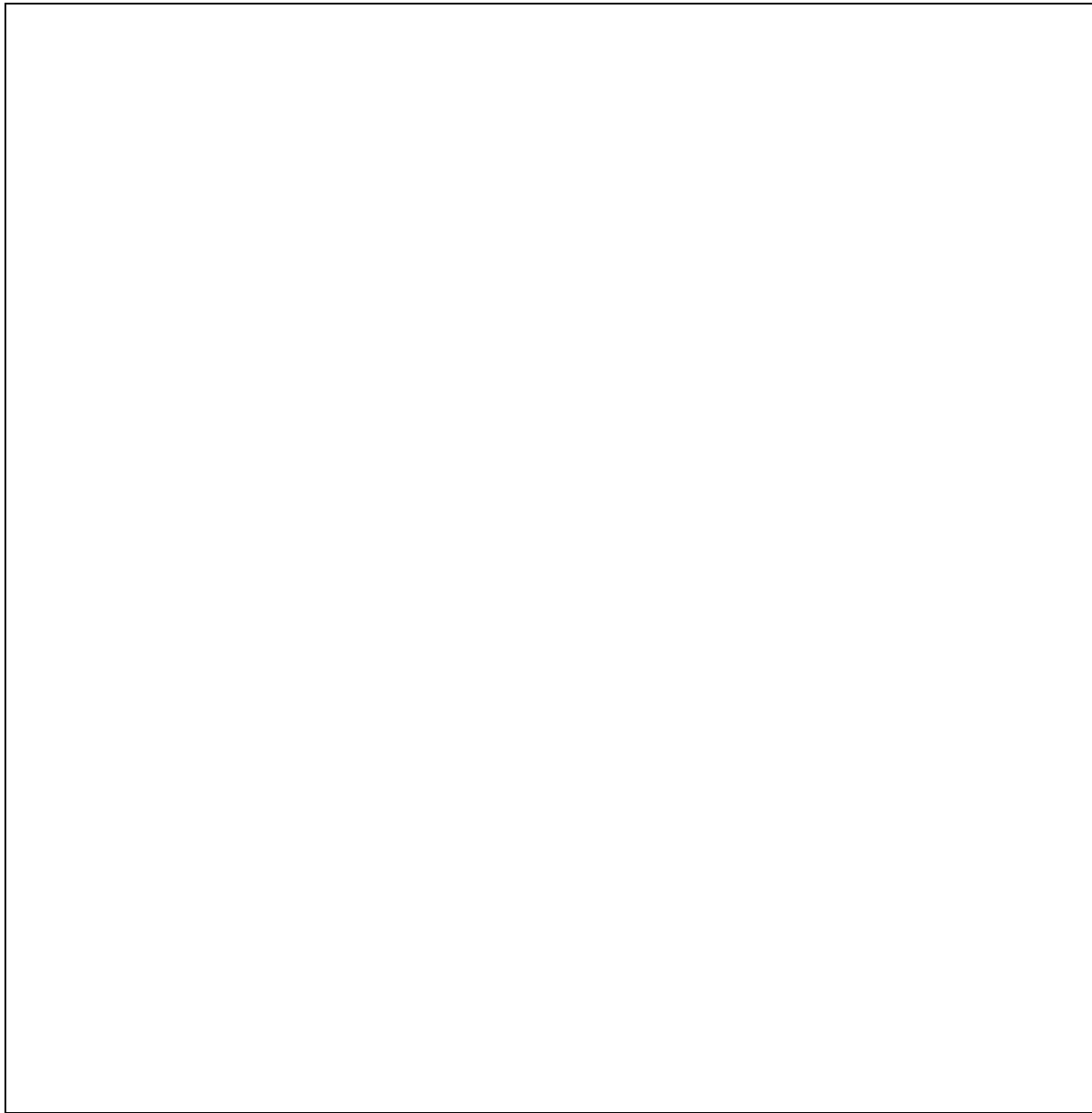
Aims/Significance (Topics 1 & 2)

Decisions the trial is intended to inform

In what setting

Who are the stakeholders?

Research question/aims

A large, empty rectangular box with a thin black border, intended for the user to write their answers to the questions listed above it.

Design (Topic 4)

Unit of randomization? (e.g., individual patient, provider, clinic)

Parallel groups, stepped-wedge?



Participants (Topic 1)

Who is eligible? (e.g. should anyone be excluded for safety reasons)

How will they be identified?

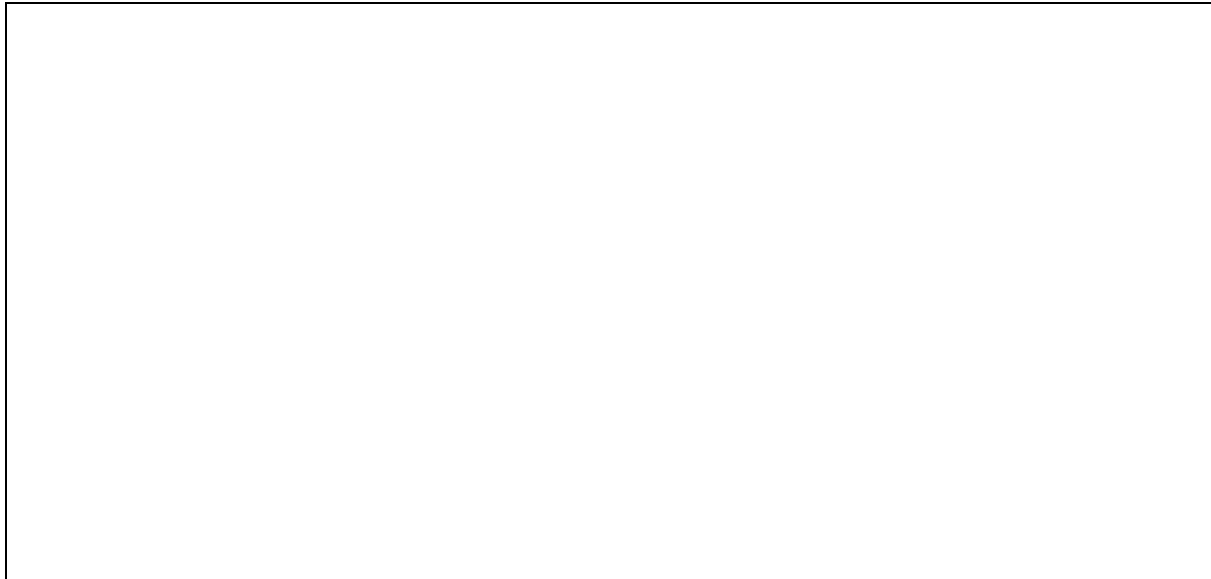


Interventions (Topics 1 & 3)

Organization: what kind of expertise is needed to deliver?

Flexibility in how intervention is delivered?


Flexibility in degree of adherence tolerated?



Outcome(s) (Topic 6)

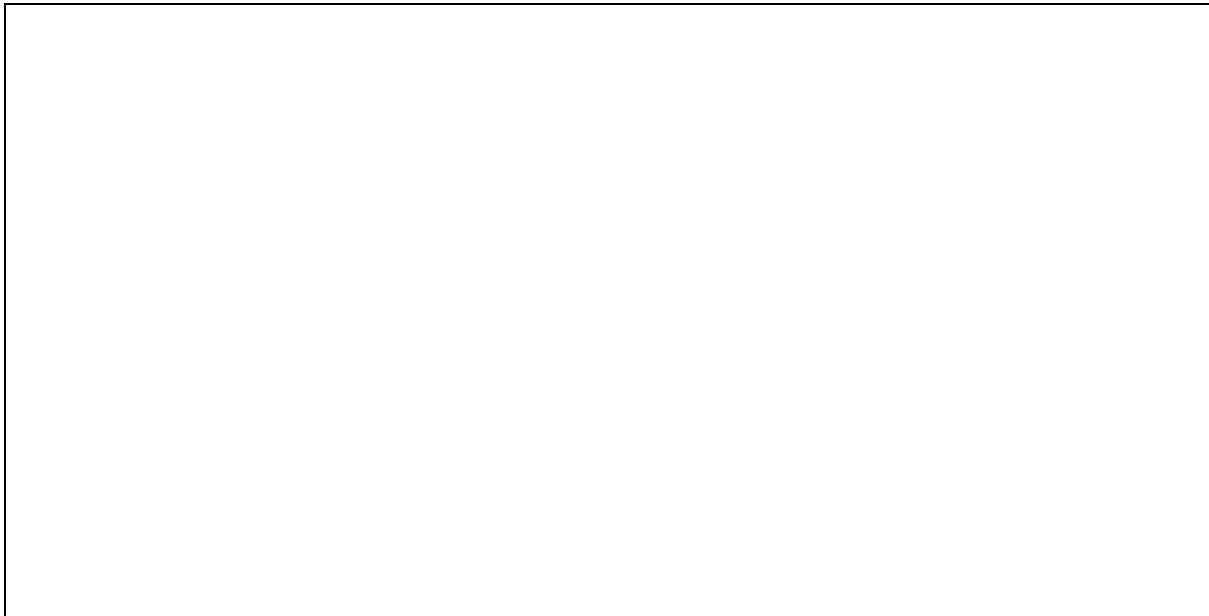
How will it be ascertained? (e.g., passive or active data collection?)

Relevance to stakeholders?



Sample Size (Topic 4)

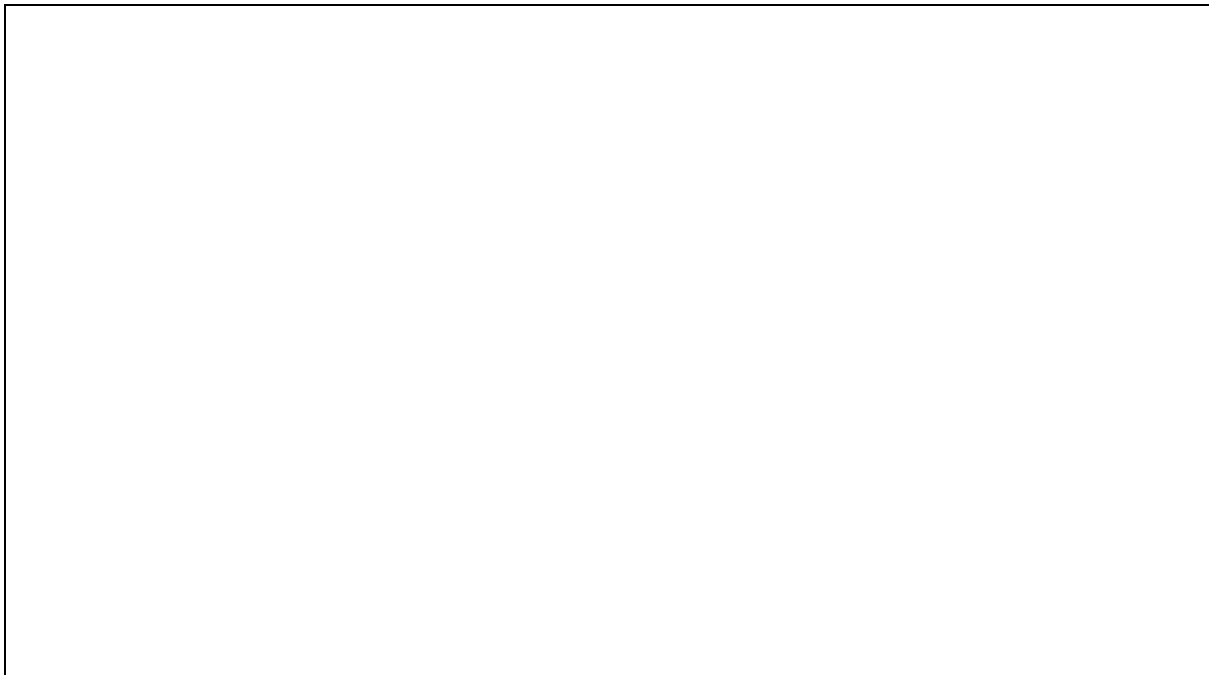
If cluster randomized, estimate of ICC?



Human Subjects Protection (Topic 5)

Who are the participants and how should they be protected?

Is written informed consent required of any participants?

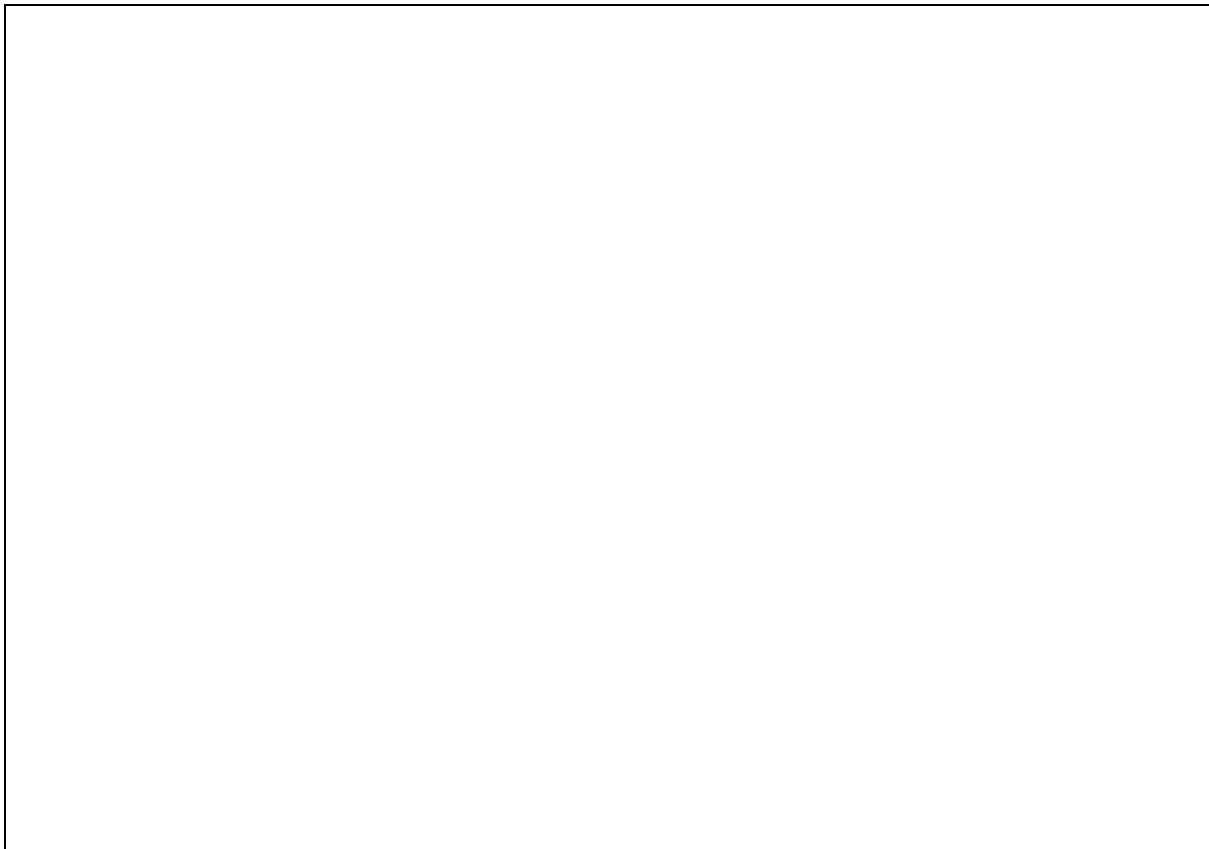


Analysis (Topic 4)

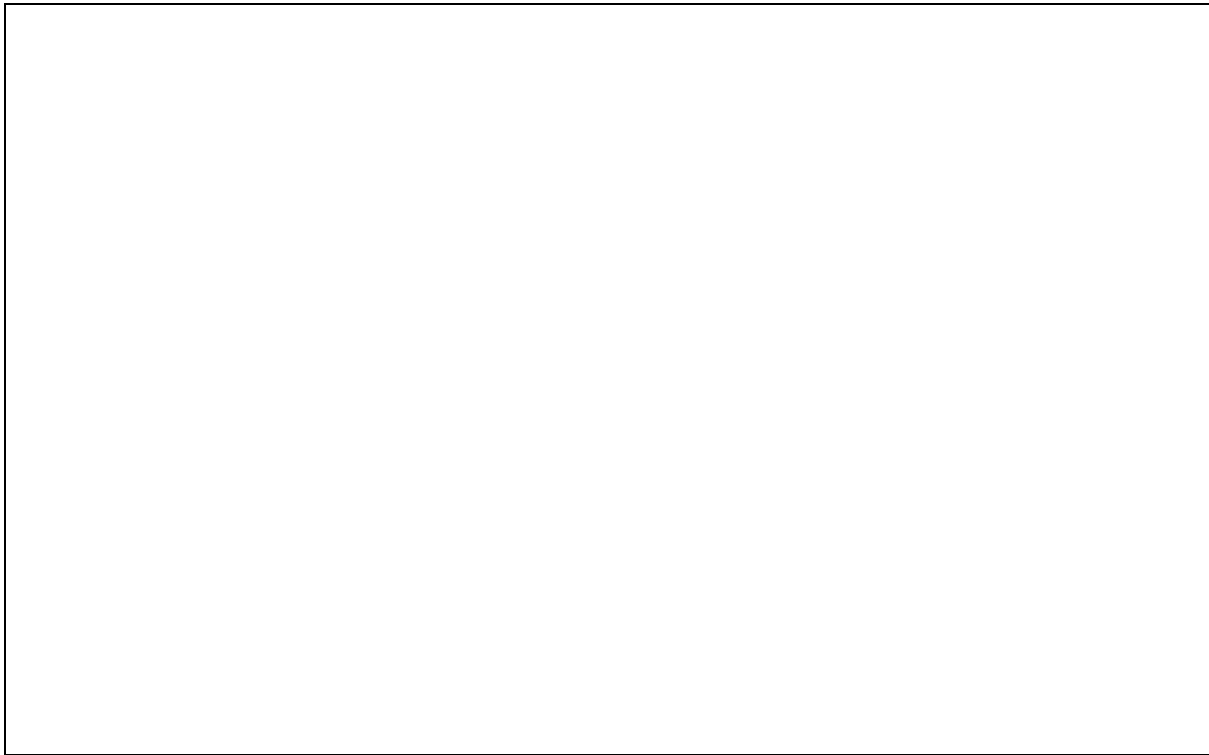
Are all observations included? (Intent-to-Treat)



Pilot/feasibility testing: What needs to be done? (Topic 7)



Dissemination/Implementation Strategy? (Topics 3 & 8)



Weaknesses and how you will manage them?

