The ACP-PEACE trial (**P**romoting **E**ffective **A**dvance **C**are planning in the **E**lderly) is a stepped-wedge cluster randomized trial (SW-CRT) of a combined advance care planning (ACP) program consisting of in-person clinician communication skills training and patient-facing video decision aids in 36 oncology clinics across three sites. After a baseline period of six months, a pair of intervention clinics at each of our three sites are trained in the intervention. The training is repeated every six months (6 months = 1 step) for six steps (6 steps x 2 clinics/step x 3 sites = 36 clinics). (See Figure 1.) The primary outcome is ACP completion rates in advanced cancer patients aged 65 years or older.

Figure 1. Original Stepped-Wedge Design of ACP-PEACE

| Clinic | Baseline | STEPS | | | | | |
		1	2	3	4	5	6
1, 2							
3, 4							
5, 6							
7, 8							
9, 10							
11, 12							

The ACP-PEACE trial successfully completed the baseline data collection and Step 1 training (2 clinics per site x 3 sites = 6 intervention clinics). However, during Step 2, COVID-19 spread throughout the country interrupting our stepped-wedge design in two respects: 1. Motivated by the disproportionate risk to cancer patients from COVID-19 and the higher mortality rates among their older patients (i.e., the cohort of patients in the ACP-PEACE trial), oncologists in both control and intervention clinics increased ACP activities artificially changing our primary outcome (ACP rates) in both control and intervention clinics (i.e., the "COVID-19 effect"); and, 2. The team was unable to conduct the in-person training for the Step 2 intervention clinics.

Following the recommendation of the NIH Collaboratory Statistics Core, we propose using our original Step 2 period as the new baseline for the remaining 30 clinics and to "restart" the trial (See Figure 2.) This would allow us to train the remaining 30 control clinics over four steps (i.e., every six months) keeping the trial completion on time.

Figure 2. Proposed New Stepped-Wedge Design of ACP-PEACE with COVID-19 Effect

Clinic	Baseline	1	2	3	4	5	6
1,2							
			Baseline	1	2	3	4
3,4,5							
6,7							
8,9,10							
11,12							

	Intervention	Covid-19
(grey)	no	no
(green)	no	yes
(light)	yes	no
(orange)	yes	yes

The data we collect from the 36 clinics will allow us to address the changes due to COVID-19. Our new specific aims now include:
Aim 1: Examine the ACP Program intervention effect prior to COVID-19: This will be done using the data from the 6 clinics from our original Step 1. We will estimate ACP rates prior to the intervention (original baseline) and after the intervention (Step 1).
Aim 2: Examine the intervention effect post COVID-19: This will be done using the data from the remaining 30 clinics. We will have the stepped-wedge design starting in the original Step 3.
Aim 3: Examine the COVID-19 effect: This will be done using the data from the remaining 30 clinics. We will estimate the ACP rate prior to COVID-19 from the original baseline and Step 1, and the ACP rate post COVID-19 using the original Step 2 data. Additionally, we can examine the time trend after the new baseline to see how the COVID-19 effect diminishes over time from control period clinics.