Sample Size and Power

The sample size was based on the ECC rates reported by Tang et al. (7). Our patient base should be similar to those sampled by Tang in terms of SES so that these estimates should be reasonable projections of the ECC rates that we can expect to see by ethnicity. An average of ECC rates for the age groups under investigation was calculated to arrive at these ECC rates. The following table summarizes the results reported by Tang et al. that we used in our sample size determination.

Age Group	**Ethnicity** African-American	**Hispanic**	**White**
2-4 years old	31%	42%	23%

Sample size was calculated for a weighted proportion with ECC based on anticipated racial/ethnic distribution in the clinics and based on a simple logistic regression model comparing intervention group to control group. The following table gives sample size estimates based on anticipated racial/ethnic distribution in the clinics as well as sensitivity analysis for deviations in the anticipated racial/ethnic distribution.

Table 1: Sample size based on weighted proportion of ECC

Ethnic Distribution							
Black - .31	50%	60%	60%	60%	40%	40%	40%
Hispanic - .42	33%	28%	33%	23%	38%	33%	43%
White - .23	17%	12%	7%	17%	22%	27%	17%
Weighted Proportion with ECC	0.3327	0.3312	0.3407	0.3217	0.3342	0.3247	0.3437
Significance Level, α	0.05	0.05	0.05	0.05	0.05	0.05	0.05
1 or 2 sided test?	1	1	1	1	1	1	1
Proportion, p_C, at mean μ of covariate $\times$	0.2828	0.2815	0.2896	0.2735	0.2841	0.2760	0.2922
At $\times = \mu + \sigma$, Proportion, p_I	0.2329	0.2318	0.2385	0.2252	0.2339	0.2273	0.2406
Odds Ratio	0.770	0.770	0.768	0.772	0.769	0.772	0.767
Coefficient, B = ln(odds ratio)	-0.261	-0.261	-0.264	-0.259	-0.262	-0.259	-0.265
Power (%)	80%	80%	80%	80%	80%	80%	80%
n	512	514	496	534	507	528	490
n – adjusted for 20% attrition	**640**	**643**	**620**	**668**	**634**	**660**	**613**
Power (%) for n=512		**79%**	**81%**	**78%**	**80%**	**78%**	**81%**

The figures in the table above are based on an anticipated 30% reduction in ECC rates when comparing the intervention group to the control group with 80% power. We believe this estimated 30% reduction is reasonable and appropriate, given that Harrison (34) and Bruerd (35) reported a 33% reduction in ECC from a community education program that also did not include the application of fluoride varnish, similar to what we

propose in this revised application. Assuming a 20% annual loss to follow-up, we would need at baseline a total of 320 children in each of the intervention and control groups (a total of 640 children based on half in each group) that we will follow for a minimum of one year. Power curves for the sample sizes in the shaded columns are shown in the following figure:

We have also estimated our sample sizes by using caries prevalence data from NHANESIII obtained from children living in poor and low-income families, which would be most similar in socioeconomic and cultural backgrounds to those children whom we would be seeing in our proposed study. Also using the assumptions alpha = 0.05, 80% power, and a one-tailed test, we estimated that we would need 373 children in each group (intervention vs. control) after two years of follow-up to detect a 30% difference in dft. As noted earlier, we then conservatively estimated an attrition rate of 20% per year for each year of follow-up, such that we would need to enroll 584 children in each group to yield 373 after two years of follow-up.

Table 2: Sample Size for Detecting 30% Change in dfs After 2 Years

Significance, α	0.05	0.05	0.05	0.05
1 or 2 tailed test?	2	1	2	1
Change in dfs under H_0, μ_0	2.215	2.215	2.215	2.215
Change in dfs under H_1, μ_1	1.551	1.551	1.551	1.551
Mean Difference, μ_d	0.664	0.664	0.664	0.664
Standard Deviation of Difference, σ_d	5.149	5.149	5.149	5.149
Effect Size, $\delta_d=\lvert\mu_d\rvert/\sigma_d$	0.129	0.129	0.129	0.129
Power (%)	80	80	90	90
n	474	373	634	516

Table 3: Sample Size for 50% Reduction in dfs Over 2 Years and for 40% Reduction in dfs Over 3 Years

	50% Reduction Over 2 Years	**40% Reduction Over 3 Years**
Significance, α	0.05	0.05
1 or 2 tailed test?	1	1
Change in dfs under H_0, μ_0	2.215	3.331
Change in dfs under H_1, μ_1	1.108	1.999
Mean Difference, μ_d	1.107	1.332
Standard Deviation of Difference, σ_d	5.149	5.149
Effect Size, $\delta_d=\lvert\mu_d\rvert/\sigma_d$	0.215	0.213
Power (%)	80	80
n	136	138