Data Analysis Plan – Project 1

Hypothesis: Lung function in children with asthma as measured by FEV is significantly improved in children treated with budesonide or nedocromil after 6 years.

Exposure:
Budesonide, nedocromil or placebo.

Outcome:
Pre-bronchodilator Forced Expiratory Volume at 1 second (FEV1)

Possible Covariates:
Gender (male, female), Ethnicity (Black, Hispanic, Other, Non-Hispanic White), age at enrollment, age of current home in years, any pets, uses a woodstove, uses a dehumidifier, whether any parent smokes, and whether anyone (including visitors) smokes in the home.

Analysis:
There are many observations for each individual ranging from 1 – 18. Some individuals have observations extending to 10 years of follow-up. Outcome will be FEV measurements at 72 mos (6 year mark), or the last measurement for those with less than 6 years of follow-up. Those with less than 4 years of follow up will be excluded.

Information on age of the home, pets, woodstoves, dehumidifiers and smokers was not collected at every visit and had the potential to change over the course of the study, therefore whether or not the child ever reported the exposure during the first 6 years of follow-up will be analyzed. Age of home will be broken into two categorical variables whether or not the child ever reported living in a home older than 50 years, and older than 100 years, over the first 6 years of follow-up.

A univariate analysis between outcomes and exposure will be performed using general linear regression. Assumptions of linearity, homoscedasticity, and normality will be confirmed using diagnostic plots.

Relationship between possible covariates and outcomes will be analyzed. Covariates with a significant association with outcome will be considered for a multivariate model. P values <0.05 will be considered significant.

Since participants were randomly assigned, there should be no relationship between possible covariates and exposure. This will be confirmed using χ^2/fisher's exact for categorical variables and ANOVA for continuous.

Analyses that have significant overall F statistics will be considered for inclusion in tables.

Tables and Graphs:
Table 1. Characterstics of Study Participants by Treatment Group

	A (n=199)	B (n=196)	C (n=264)	p-value
	N(%)	N(%)	N(%)	
Gender				0.02
Male	117(59)	131(67)	142(54)	
House >= 50				0.69
Yes	68(34)	64(33)	96(36)	
House >= 100				0.94
Yes	10(5)	10(5)	15(6)	
Pets				0.44
Yes	171(86)	176(90)	228(86)	
Woodstove				0.86
Yes	24(12)	22(11)	34(13)	
Parents Smoke				0.72
Yes	73(37)	65(33)	89(34)	
Anyone Smokes				0.55
Yes	83(42)	73(37)	98(37)	
Ethnicity				0.93
Black	27(14)	26(11)	33(8)	
Hispanic	20(13)	22(9)	24(66)	
Other	20(12)	17(10)	20(67)	
Non-Hispanic White	132(10)	131(9)	187(71)	
	Mean(SD)	Mean(SD)	Mean(SD)	
Age at Enrollment	8.5(2.1)	8.2(2.2)	8.3(2.2)	0.40
Baseline FEV	1.7(0.4)	1.6(0.5)	1.7(0.5)	0.38
Month of Visit	70(6)	70(6)	70(6)	0.78