

Title: Immune response to influenza vaccination and effect on reproductive hormone

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The power calculations are based on specific aim 1, with regards to changes in progesterone.

SA1: To determine if vaccination with IIV prior to ovulation (day 11 of menstruation) is associated with changes in post-ovulation serum reproductive (progesterone and estradiol) hormone concentrations. *-H 1: Post-vaccination serum progesterone concentrations will be lower in the month after vaccination than measured prior to vaccination.*

We are planning to study 30 adult non-pregnant women each year. Based on the results from the first 30 student enrollees, we estimate the log (base 10) mean (SD) serum concentration of progesterone during the luteal phase of menstruation prior to vaccination is 0.71 (\pm 0.51), and 0.58 (\pm 0.54) post vaccination. This difference of -0.13 on the log (base 10) scale corresponds to a median ratio of 0.74 in other words, a 26% decrease in median progesterone levels after vaccination. The observed correlation in these log concentration values was 0.60. For a total sample size of 90 women (base task order and 2 option years), assuming similar standard deviation in log (base 10) pre- and post- vaccination values as observed in the initial sample of 30, the following table shows to the power to detect a given median post-vaccination to pre-vaccination concentration ratio for several pre- and post- concentration correlation values. These results are based on a type-1 error level of .05.

	Correlation		
Median Ratio	0.55	0.60	0.65
0.75	<i>0.63*</i>	<i>0.69</i>	<i>0.74</i>
0.70	<i>0.82</i>	<i>0.86</i>	<i>0.90</i>
0.65	<i>0.93</i>	<i>0.95</i>	<i>0.97</i>

* values in italics give estimated power to detect the specified median ratio for a specified correlation between the pre- and post-vaccination progesterone values