

Attachment 4.b. Summary of Published Prospective Pregnancy Studies with Preconception Enrollment

Primary Author (Country)	Length of Follow-up	Daily Diaries	Urine Samples	Blood Sample(s)	Semen Sample(s)	Dropped Out of the Study	Incentive(s) to Participate
Bonde (Denmark)	6 cycles or until pregnancy occurred	1,329/1,657 completed (80%)	9,671 (83%) women; 820 (59%) men	women: 288/317 (91%) men: 350/376 (93%)	418/430 (97%)	35 (8%)	\$200 for specimens; participants entered in a lottery for \$3,000 ^b
Brown (United States)	12 cycles, 2nd miscarriage, or delivery if pregnancy occurred ^b	N/A	N/A	N/A	N/A	510 (44%)	\$100 for completion and small gifts (e.g. pencils) with newsletters
Buck (United States)	12 cycles, or until 1st postpartum visit or cessation of breastfeeding (if nursing)	7 women missing 1+ weekly cards ^b	N/A	88/102 (86%)	N/A	20 (20%)	\$50 for completion through postpartum blood & breast milk (97% of women provided a postpartum breast milk; 74% provided a second sample upon weaning) ^b
Colombo (Europe)	Average of 8.6 cycles per woman	80.6% included BBT, 85.2% included cervical mucus score ^b	N/A	N/A	N/A	300 (25%) 84 of these women re-entered ^b	None ^b
de Mouzon (France)	12 cycles or until delivery	^a	N/A	N/A	N/A	687 (36%)	^a
Elish (United States)	12 cycles or until pregnancy occurred	1304/1516 (86%) completed ^b	95%	N/A	N/A	7%	\$10 for every 2 months of participation; lab results were forwarded to physicians ^b
Eskenazi (United States)	6 cycles or clinical pregnancy	403 (84%) completed at least one cycle ^b	84% completed at least one cycle ^b	N/A	N/A	78 (16%)	\$35 for each month of participation; eligible for a prize drawing for a trip to Hawaii or other local resort
France (New Zealand)	6 months or until pregnancy occurred	91 (38%) completed the entire protocol ^b	^a	N/A	N/A	148 (62%)	Personal instruction regarding fertility awareness and the Shettles theory of sex selection ^b
Hakim (United States)	At least 6 months or until pregnancy occurred (mean = 7 cycles)	Near 100% ^b	90%	N/A	N/A	24 (16%) ^b	\$100 for completion of the study; feedback on menstrual cycles

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Sweeney (United States)	12 months or until pregnancy occurred	^a	Among those conceiving, 84% provided daily urines (88% weekly urines)	N/A	N/A	45 (55%)	None ^b
Sweeney (United States)	3 cycles or until the end of the 1st trimester if pregnancy occurred	81%	80%	N/A	N/A	^a	None ^b
Vartiainen (Finland)	6 months or until pregnancy occurred	88% 1 st f/u; 59% 2 nd f/u; 39% 3 rd f/u ^b	N/A	N/A	180 (94%) ^b	11 (6%)	None ^b
Wang (China)	12 months or clinically confirmed pregnancy after stopping contraception	545 (57%) completed at least one cycle ^b	545 (57%) completed at least one cycle ^b	N/A	N/A	35 (4%)	\$1 per 3 urine samples ^b
Wilcox (United States)	6 months or until pregnancy occurred	98% ^b	98%	N/A	N/A	6 (3%)	\$10/week for urine collection
Zinaman (United States)	12 months or until pregnancy occurred	Over 90% ^b	Over 90% ^b	^a	100% (requirement for participation)	8 (4%)	\$500 for completion of the study

NOTE: Cycles refer to menstrual cycles while months refer to calendar time. Adapted from Buck et al., 2004.

^a = Information not available. ^b = Personal communication with author(s).

N/A = Information not applicable (i.e., did not estimate target population, enroll male partners (couples), collect specimen(s), as appropriate)

f/u = Follow-up

Adapted from: Buck GM et al. Prospective Pregnancy Study Designs for Assessing Reproductive Developmental Toxicants. Environmental Health Perspectives 2004;112:79-86