

STUDY OF CORTISOL AND PULMONARY FUNCTION

*See PFT
data set*

PROTOCOL FOR SUBJECT RECRUITMENT AND DISTRIBUTION OF QUESTIONNAIRES AND URINE COLLECTION MATERIALS

1. SUBJECT IDENTIFICATION

All subjects in the Offspring Cohort returning for their regularly scheduled visits to FHS, who live within the "Framingham Taxi Area" (consisting of Framingham and towns contiguous to Framingham as outlined in the map found in the clinic), or who work in Framingham, are eligible to participate in this study.

Eligible subjects will be identified prior to their clinic visit by reviewing the roster. These people will be recruited at the beginning of their visit, and if they agree to participate, their name tag will be marked with yellow highlighter.

2. SUBJECT RECRUITMENT

Eligible subjects (as identified by their place of residence as described above) will be recruited by a member of the clinic staff at the beginning of their visit. The study will be described and the urine collection procedure will be explained to the subject. If (s)he agrees to participate, the urine collection materials will be given to her(him) at this time and her(his) name tag will be marked with yellow highlighter to alert the phlebotomist to draw the two extra tubes of blood.

A log will be kept, recording each participant's name, ID number, date of clinic visit, and if refused to participate, the reason for the refusal.

3. URINE COLLECTION KIT

A urine collection kit will be given to each subject who agrees to participate in this study. Subjects will be given a brief explanation of how to collect the urine.

The kit consists of:

1. a 3.5-liter specimen bottle with cap, labelled with the subject's name and ID #, with summary instructions taped to the bottle
2. an 8-ounce specimen cup
3. a form with "Instructions for 24-hour Urine Collection" on one side, and "24-hour Urine Sample Collection Form" on the reverse side, with the subject's name, ID#, and date of clinic visit

4. NOTIFICATION OF THE LABORATORY

If any subjects who previously agreed to participate (and therefore had blood drawn) are unable to complete the Pulmonary Function Test or change their mind about the urine collection, the laboratory will be notified so that they do not send the blood out for analysis.

5. RESPIRATORY QUESTIONNAIRE (RQ)

A copy of the RQ will be given to each member of the Offspring Cohort to complete at the time of his/her regular clinic visit. All subjects will complete the RQ, regardless of their participation in the Cortisol Study. The subject's name and ID# will be entered on the top of the RQ.

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6. DELIVERY OF URINE SAMPLES AND QUESTIONNAIRES

The participants will drop off the urine collection and the urine sample collection form in the designated container at the FHS. The urine sample will be taken to the lab for processing by the laboratory personnel.

7. ASSESSING PARTICIPATION

Subjects who fail to deliver a specimen within 2-3 weeks will be contacted by telephone and encouraged to complete the urine collection.

8. REVIEWING THE RESPIRATORY QUESTIONNAIRE

Questionnaires will be reviewed for completeness. Subjects who have left questions unanswered will be contacted by telephone, and answers to incomplete items solicited by directly questioning the subject; if the subject is uncertain of the answer, choose 'NO'.