

TO: CHRONIC PROSTATITIS COHORT STUDY
CLINICAL CENTERS
PRINCIPAL INVESTIGATORS

FROM: LEE RANDALL

SUBJECT: CPC PROTOCOL AMENDMENT – VISIT SCHEDULE

DATE: 3/16/01

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CHRONIC PROSTATITIS COLLABORATIVE RESEARCH NETWORK
CHRONIC PROSTATITIS COHORT (CPC) STUDY

PROTOCOL #

PRINCIPAL INVESTIGATOR:

DEPARTMENT:

AMENDMENT TO CPC VIST SCHEDULE

**CURRENT PROTOCOL STATUS FOR CPC PATIENT FOLLOW-UP
SCHEDULE** (*Section 3.3 of CPC Study Protocol*)

Brief Clinic Visit

3.3.2 Brief Clinic Visit (Month 6, 18, and 30)

Currently, during months 6, 18, and 30 after initial enrollment in the follow-up phase, the patient will have a clinic visit, in which he will provide the research staff with the requested information and undergo the procedures identified below.

1. Symptom/Impact/General Quality of Life Index
2. Interim Health Care Assessment. The research staff will request information regarding any non-chronic prostatitis related medical events, surgical procedures and hospitalizations that occurred since the last clinic visit. The patient will also provide the research staff with information regarding recent prostatitis treatment.
3. Urinalysis, urine and EPS microscopy.

4. Physical exam. The patient will have a focused physical exam as indicated by the physician.
5. Visit closeout.

Appointment scheduling. An appointment will be made for the next scheduled contact.

Yearly Clinic Visit

3.3.3 Yearly Clinic Visit (Month 12, 24 and 36). Currently, during months 12, 24 and 36 after initial enrollment in the follow-up phase, the patient will have an annual clinic visit, in which he will provide the research staff with the requested information and undergo the procedures identified below.

1. 1-day Voiding Log.
2. Symptom/Impact/General Quality of Life Index
3. Interim Health Care Assessment. .
4. Physical exam.
5. Urinalysis, urine and EPS specimens for microscopy and culture.
6. Visit closeout.

Appointment scheduling. An appointment will be made for the next scheduled contact.

PROPOSED CHANGES TO CPC PROTOCCOL VISIT SCHEDULE

The above listed **Brief Clinic Visit at month 30** and the **Yearly Clinic Visit at month 36** have been changed to a telephone and mail contact. These contacts will exclude the following laboratory procedures:

- Urinalysis and EPS microscopy
- Physical examination
- Interim Health Care Assessment

All Brief Clinic and Yearly Clinic Visits will not continue beyond month 24.

Brief Clinic Visit closeout will be at month 18 and Yearly Clinic Visit closeout will be at month 24.

Months 30 and 36 telephone/mail contact will include the following indices:

- Symptom/Impact/General Quality of Life Index
- 1-day voiding log (**Month 36 only**)