# 1 General Information

## 1.1 Study Organization

The Chronic Prostatitis Clinical Research Network (CPCRN) consists of the six Clinical Centers (CC) and one Data Coordinating Center (DCC), as specified in the Chronic Prostatitis Cohort (CPC) Manual of Operations.

## 1.2 Control Group Study Objectives

Each Clinical Center is responsible for enrolling 20 normal, healthy males into the CPC Control Group Study, age-matched to the CPC Study as outlined in the protocol. Each participant will complete two clinic visits, comparable to the Screening Contact for the CPC Study. There will be no follow-up after the completion of the second visit.

## 1.3 Informed Consent

Each Clinical Center is responsible for obtaining IRB approval and explaining the CPC Control Group Study requirements and administering the Informed Consent to all potential study participants. The Informed Consent must be signed before any forms are completed or any study procedures are performed.

## 1.4 Patient Confidentiality

Extensive efforts will be made to ensure that the participant's confidentiality is maintained. Each participant will be assigned a unique identification number. A log of the participants' names and ID numbers will be kept in a locked file cabinet at each CC. The DCC will not have access to this log. Only the participant's ID number and initials will be known to the DCC, and entered onto the CRFs and into the database. Any communication between the CC and the DCC regarding the participant will be through this ID number and initials.

## 1.5 Compensation

All volunteers will be compensated for their participation in the CPC Control Group Study. It is recommended that participants be paid $50 at the end of the first visit, and $250 at the end of the second visit, for a total of $300.

## 1.6 Assigning Patient ID Numbers

Each CC will be assigned a Participant Log. This log will document the patient ID number, initials, name, and date of informed consent. Each ID number may only be used once. If a participant is assigned a Patient ID, and later withdrawals or is removed from the study, this number cannot be used again.

The Patient ID is a five-digit ID number. The first digit of the Patient ID for all participants in the CPC Control Group Study will be 2. The second digit of the Patient ID corresponds to the CC, as follows:

1 = Brigham and Women's Hospital
2 = Temple University
3 = University of Maryland
4 = Northwestern University
5 = UCLA
6 = Queen's University, Canada

The last three digits of the Patient ID are assigned sequentially to each participant as he enters the study.

*Example:* *24001 – CPC Control Group Study participant #1 at Northwestern University.*

The Participant Log contains personal identifying information, and should remain at the clinical center. It should not be sent to the DCC.

## 1.7 Participant Eligibility

Each participant must meet the eligibility criteria in order to participate in the CPC Control Group Study. The study eligibility criteria consist of the following, and are contained in the Inclusion and Exclusion Checklists.

*Inclusion Criteria*

- Patient or parent/legal guardian has signed and dated the informed consent
- Patient is a male

*Exclusion Criteria*

- In the past year, patient has experienced symptoms of discomfort or pain in the pelvic region for any extended period of time
- Patient has a history of prostate, bladder, or urethral cancer
- Patient has inflammatory bowel disease (such as Chron's disease or ulcerative colitis, but not irritable bowel syndrome)
- Patient has undergone pelvic radiation or systemic chemotherapy
- Patient has undergone intravesical chemotherapy
- Patient has been treated with intravesical BCG
- Patient has unilateral orchialgia without pelvic symptoms
- Patient has an active urethral stricture
- Patient has a neurological disease or disorder affecting the bladder
- Patient has undergone TURP, TUIP, TUIBN, TUMT, TUNA, balloon dilatation of the prostate, open prostatectomy, or any other prostate surgery or treatment such as cryotherapy or thermal therapy

- Patient has a neurological impairment or psychiatric disorder preventing his understanding of the consent and his ability to comply with the protocol
- Patient has been treated with antimicrobial agents (oral or parenteral) in the past three months
- Patient has had a urinary tract infection with a urine culture value of >100,000 CFU/mL within the past three months
- Patient has had any of the following sexually transmitted diseases (STDs) in the past three months: gonorrhea, chlamydia, mycoplasma, trichomonas
- Patient has had a prostate biopsy in the past three months
- Patient has experienced symptoms of acute or chronic epididymitis within the past three months
- Patient has been diagnosed with or treated for symptomatic genital herpes in the past twelve months

# 2 Acquiring and Submitting Case Report Forms

## 2.1 Acquisition of Case Report Forms (CRFs)

All CRFs, including data collection forms and administrative forms, will be made available as .pdf files on the CPCRN Computer at each CC. The Research Coordinator (RC) is responsible for printing and assembling the forms for each participant.

## 2.2 Submitting CRFs to the DCC

All original CRFs should be kept at the CC in the participant's study binder/folder. The DCC may request copies of forms throughout the study. All forms requested by the DCC should be sent via traceable courier, preferably FedEx.

Forms should be sent to:

University of Pennsylvania School of Medicine
Clinical Research Computing Unit
423 Guardian Drive
Blockley Hall, 5th floor
Philadelphia, PA 19104-6021

Attn: Elizabeth Phillips, CPCRN Data Manager

When a participant's contact packet is requested, the entire packet, including the checklist and the Data Processing Cover Sheer, and source documentation (lab reports for the study procedures) should be sent. *Responses to CRCU requests are expected in a timely fashion.*

Copies of completed forms or lab results sent to the DCC should ***never*** contain participant names.

# 3 Completion of Case Report Forms

## 3.1 General Instructions for Completion

The form heading is in the upper right corner of each form. The six data fields in this box are essential and *must* be completed on every CRF. The information provided in this heading ensures identification of data should CRFs become separated. *This is the first step in completing every CRF*.

The form heading contains the follow essential information:

**Patient ID:** This five-digit number is the unique identifier assigned to each study participant. It should be written on all study documents and specimens.

**Patient Initials:** The participant's two or three initials serve as a check on the ID number and as a quality control check on forms and specimens.

**Clinical Center:** Each clinical center is assigned a unique code number, as specified previously (*Assigning Patient ID Numbers*).

**Contact Month:** This is included to correspond to the CPC CRFs. For the Control Group Study, the Contact Month will always be 0, as it is comparable to the Screening Contact (contact month = 0) for the CPC Study.

**Date:** Record the date the form was completed (mm/dd/yy format). The exception to this standard is the EXAM, FGTM, FGTSC, SERUM, URO, SWAB, and SEMEN forms. For these forms, the Date should reflect the date of the procedure or test.

**RC ID:** This RC ID for each RC is the last four digits of the RCs Social Security Number, or the ID assigned by the DCC upon request.

All forms must be completed by the RC, PI or other authorized study personnel. Underneath the CPC Control Patients heading is a subheading which indicates by whom the form is to be completed. These are described as follows:

> **Patient Completed**: To be completed solely by the patient.
> **Patient Interview Completed**: To be administered to the patient by the RC by asking the specific questions of the patient and recording the answers on the CRF.
> **Research Coordinator Completed**: To be completed by the RC
> **Research Coordinator and Principal Investigator Completed**: To be completed by both the RC and the PI, or PI designee.

The following guidelines are applicable to all CRFs being completed for the CPC Control Group Study:

- Print legibly and clearly, using a ballpoint pen with *black* ink
- Do not use correction fluid
- Dates must match source documentation
- Always use participants' initials, not full names
- Provide signature and dates on forms where required

- Include identifying information on all forms (Patient ID, Initials, Clinical Center, Contact Month, Date, and RC ID)
- Completely fill out the upper right hand corner on all forms.
- Copies of lab reports and other source documents must be clear and legible.

If an error is identified on a form, the error should be corrected by crossing out the incorrect response with a single line in black ink, and entering the correct information. Always initial and date the change. Circle the correct answer for clarification, if necessary.

Comments, descriptions, and other free text fields are for explanations or supporting information, and will not be entered into the database. Review all forms for legibility and accuracy *before* entering and verifying them in the database. If forms are incomplete or missing due to pending laboratory data, wait until they are complete before entering them into the database. If a form or laboratory value is missing because of lab error or other reason, indicate this by writing "UNK" in the value spot. An explanation must also be indicated (in the margin or underneath the question on the form) and must be initialed and dated.

## 3.2 Data Collection Forms for the CPC Control Group Study

Each data collection form is comparable to the forms used during the Screening Contact for the CPC. The forms are matched as follows:

| CPC forms | CPC – Control Patient Forms |
|---|---|
| Inclusion Checklist (INCL) | Inclusion Checklist (INCL)** |
| Exclusion Checklist (EXCL) | Exclusions Checklist (EXCL)** |
| Deferral Checklist (DEF) | |
| Symptom Index (SXIND) | Symptom Index (SXIND)* |
| Medical History (MED) | Medical History (MED)* |
| Prior Treatments and Procedures (PRIOR) | *none* |
| Physical Exam (EXAM) | Physical Exam (EXAM) |
| Four Glass Test Microscopy (FGTM) | Four Glass Test Microscopy (FGTM) |
| Four Glass Test Specimen Cultures (FGTSC) | Four Glass Test Specimen Cultures (FGTSC) |
| Serum Sample (SERUM) | Serum Sample (SERUM) |
| Voiding Log (VOID) | Voiding Log (VOID) |
| Concomitant Medications (CMED) | Concomitant Medications (CMED)** |
| Epidemiologic History (EPI) | Epidemiologic History (EPI)* |
| Uroflow Study (URO) | Uroflow Study (URO) |
| Urethral Swab (SWAB) | Urethral Swab (SWAB) |
| Semen Sample (SEMEN) | Semen Sample (SEMEN) |
| Screening Confirmation (SCR) | *none* |
| | Contact Completion (COMP)** |

* The forms marked with a single star have been modified slightly from the CPC forms. Questions referring specifically to prostatitis and the CPC have been shaded over (Question). These questions should not be asked of or answered by the participant.

Symptom Index (SXIND):

Question #10 is asked during the CPC only at follow-up contacts. Since there will be no follow-up for the CPC Control Group Study, this question is unnecessary.

Medical History (MED):

Questions #1 and #2 specifically refer to the patient's past and current episodes of prostatitis. Since the control patients do not suffer from chronic prostatitis, these questions are not applicable.

Epidemiologic History (EPI):

Questions #14 and #15 refer specifically to the patient's prostatitis symptoms and the CPC study. These questions are not applicable to the control patients.

** The forms marked with a double star have been modified or combine more than one form.

Inclusion Checklist (INCL):

The inclusion criteria have been modified from the inclusion criteria of the CPC Study, as noted in the protocol and in the MOP (*Participant Eligibility*). The third criteria, requiring pain/discomfort in the pelvic region has been removed.

Exclusion Checklist (EXCL):

The exclusion criteria have been modified from the criteria of the CPC Study, as noted in the protocol and in the MOP (*Participant Eligibility*) The criteria include the original exclusion and the deferral criteria, as well as a requirement to exclude men with a history of pain/discomfort in the pelvic region.

Concomitant Medications (CMED):

The CPC Control Patients CMED form combines the list of medications/ treatments from the CPC Concomitant Medications form as well as the Prior Treatments and Procedures form.

Contact Completion (COMP):

The Contact Completion form is a new form specifically for the Control Group Study, similar to the Patient Completion from the CPC Study. This form should be completed by the RC, and signed and dated by both the RC and the PI, when all the forms are complete, to ensure that all data collected is accurate.

For further instructions on completing all CPC Control Group Study forms, see Chapter 7 of the CPC Study MOP.

Four Glass Test Specimen Cultures (FGTSC)

The 5-day count of specimens (organisms or "*bugs"*) and colonies are to be documented as ***additional*** growth. Any new organisms seen, or an increase in the number of colonies for a previously (at 48 hours) identified organism should be recorded. If there is no new growth, the question should be answered "No".

Semen Sample (SEMEN)

The 5-day count of specimens (organisms or "*bugs"*) and colonies are to be documented as ***additional*** growth. Any new organisms seen, or an increase in the number of colonies for a previously (at 48 hours) identified organism should be recorded. If there is no new growth, the question should be answered "No".

## 3.3 Administrative Forms for the CPC Control Group Study

The following are the administrative forms designed to facilitate the CPC Control Group Study:

Contact Checklist
Data Processing Cover Sheet
How to Complete Your Voiding Log
Lab Tracking Log
Telephone Log
Uroflow Study – Patient Information

For instructions on completing each of these forms, see Chapter 7 of the CPC Study MOP. Further instructions specific to the CPC Control Group Study are outlined below.

Contact Checklist:

The checklist is a modified version of the Screening Contact Checklist from the CPC Study. It outlines all the forms and procedures that need to be done as part of the contact. All procedures or forms from the CPC Study that are not part of the CPC Control Group Study are shaded over. This form is required to be completed and kept with the participants' study documentation.

Participant Logs:

This form contains a list of all the participants enrolled in the CPC Control Group Study, and identifies each patient's name, initials, ID number, and date of informed consent. This log is for CC use ***only***, and should ***not*** be forwarded to the DCC. The Participant Log must be stored in a secure location. See *Assigning Patient ID Numbers* for more information.

# 4 CC and DCC Responsibilities

## 4.1 Clinical Center Responsibilities

Clinical Center Staffing Requirements

Each clinical center is responsible for maintaining the staff necessary to perform all the tasks associated with the CPCRN protocols, including the CPC Study and the CPC Control Group Study. Every effort should be made to retain the Research Coordinators throughout the course of the study, however, if a RC chooses to leave, it is the responsibility of the PI to hire a replacement as soon as possible. The departing RC, if possible, and the DCC staff will be responsible for training the new RC on the CPCRN studies.

Clinical Center Obligations

It is expected that each clinical center will manage the CPC Control Group Study with integrity, professionalism, and confidentiality, and will adhere to all GCP guidelines. RCs are expected to provide the most complete, accurate data possible. PIs are expected to also review CRFs and lab results. Responsibilities of the CC staff include:

- Recruiting and enrolling participants into the study.
- Confirming the eligibility of each patient to be enrolled into the study as defined by the study protocol.
- Adhering to the study protocol and Manual of Procedures in the implementation of the procedures and collection of data.
- Collecting data of high quality

Clinical Center Regulatory Documentation

Each CC is responsible for providing the appropriate IRB with all necessary materials, including a copy of the informed consent. Approval of the protocol and informed consent must be obtained and forwarded to the sponsor prior to screening or enrolling any patients.

The CC must maintain documentation of appropriate licensure or accreditation for all clinical laboratory facilities used for study samples analysis.

Each CC must retain, on-site and in an orderly fashion, for a period of no less than seven (7) years, and make available to the sponsor or sponsor's representative, the following documents:

- signed study protocol
- amendments
- informed consent documents
- investigator brochure
- approval letters from the IRB
- treatment accountability forms
- CRFs

- all primary source documentation
- all letters of correspondence
- CVs for all PIs and RCs participating in the study at that clinical center. These must not be older than two years.
- signed form #1572
- MOP

## 4.2 Data Coordinating Center Responsibilities

The DCC will provide data entry capabilities and project and data management, computing, and biostatistical leadership for the design and conduct of the study. Responsibilities include:

- Overall leadership regarding study design, and conduct of the study.
- Preparation of the study protocol, MOP, and CRFs, based on collaboration with the Steering Committee and NIH Project Scientists.
- Collaborate with study investigators in the development, testing, and use of all CRFs and study procedures.
- Provide an efficient Data Management System (DMS) for data entry, verification, and reporting for each Clinical Center.
- Development and application of quality assurance procedures including data tracking, validation, querying, and reporting.
- Training for CC staff and coordination of site monitoring,
- Collaborate with study investigators in the analysis and publication of results.

## 4.3 Maintenance, Disposition, and Distribution of Study Documents, Data, and Materials

The DCC will be responsible for maintaining a record of all study documents, reports, and meeting minutes pertaining to the CPCRN and CPC Control Group Study. For this study, the DCC will maintain responsibility for the distribution of the MOP and all CRFs to the clinical centers.

At the close of the study, all CRFs on file at the CCs, without personal identifiers, will be archived and stored, as arranged by the CPCRN. The CCs will maintain a file on each participant, which will become a part of the participants' medical records.

All study records must be maintained for a period of seven (7) years.