Division of Preventive Medicine at UAB

Complementary and Alternative Medicine for Urological Symptoms

Manual of Operations

MANUAL OF OPERATIONS

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INTRODUCTION

The Complementary and Alternative Medicine for Urological Symptoms (CAMUS) is a double-blind, randomized, multi-center trial to determine if *Serenoa Repens* reduces the AUA symptom score in patients with benign prostatic hyperplasia (BPH) as compared to placebo over 72 weeks of treatment. Eligible participants will be randomized equally to one of two treatments: extract of *Serenoa Repens* or placebo. Participants will be treated for 72 weeks

Study Rationale

The long-term efficacy and side effects of over-the-counter phytotherapies for men with lower urinary tract symptoms attributable to BPH are unknown, despite wide use of these agents by older men for maintaining "prostatic health." The overall goal of this study is to compare the efficacy of a widely available phytotherapy, extract of *Serenoa Repens*, against placebo in terms of their impact on lower urinary tract symptoms. The phytotherapy selected for study has demonstrated short-term efficacy at relieving lower urinary tract symptoms with minimal side effects in a number of clinical trials. However, a recent NIDDK/NCCAM supported trial of *Serenoa Repens* at the 320 mg daily dose versus placebo did not demonstrate efficacy in terms of symptom reduction over 12 months of follow-up. As a result, this study is being conducted to compare higher-than-standard (double and triple) doses of this agent to determine its short-term effect on lower urinary tract symptoms and other parameters of BPH disease severity, and whether there is sufficient short-term efficacy and tolerability to merit testing for long-term efficacy in a long-term trial focused on the prevention of BPH progression. Because the study arm will use doses of this agent higher than generally used, participants will be monitored closely for toxicity/tolerability and have their doses slowly increased at 24-week intervals.

PRIMARY RESEARCH QUESTION

The primary objective of Complementary and Alternative Medicine for Urological Symptoms (CAMUS) is to determine if *Serenoa Repens* reduces the American Urology Association (AUA) symptom score compared to placebo over 72 weeks of treatment and is well tolerated.

SECONDARY RESEARCH QUESTIONS

Key secondary objectives of the study are to:

1. Determine if *Serenoa Repens* has a beneficial effect on subjective global assessment.

2. Assess the impact of *Serenoa Repens* on the following measures over time:
    a. BPH Impact Index
    b. Quality of Life item score from the IPSS
    c. Nocturia item score from the IPSS

d. Peak uroflow
e. Post-void residual volume
f. Prostate Specific Antigen (PSA) level
g. Erectile and ejaculatory function
h. ICS*male* Incontinence scale
i. Jenkins Sleep Dysfunction scale
j. NIH Chronic Prostatitis Symptom Index

3. Assess the impact of the assigned treatment on complete blood counts and basic blood chemistries.

RECRUITMENT STRATEGIES

Coordinators involved in clinical research have the often-difficult task of recruiting potential study candidates for clinical trials. Below is a list of participant recruitment strategies that may be helpful. Before implementing these strategies, Clinical Center staff should consult with their IRB to find out if IRB approval will be needed and obtain IRB approval if required.

The study requires enrolling a total of 380 participants in six months. Each site must recruit 35 participants during the enrollment period. This translates to about six patients a month or more than one patient a week. Experience from previous trials suggests that recruitment strategies that focus on urology clinics will not yield eligible patients. Given the exclusion criteria for the study and the large number of medications that are part of the exclusionary list, it is important to target individuals who are treatment naïve. It may also be important to de-emphasize the complimentary and alternative aspect of the trial and focus on the BPH since earlier trials also suggest that men were interested in CAM but were not true believers. Some of the strategies that have been used successfully to recruit participants from the community include:

1) Advertising: print media, e.g., local newspapers (sports and business sections), local “Freebie” papers, esp. back page, programs at sporting events and hospital/health plan newsletters

2) Advertising: other media, e.g., Public Service Announcements (PSA)- some radio stations and local TV stations will run for free for a short time, some radio stations actively solicit these, sports radio, ads on local public transportation and “Above the Urinal” ads.

3) Social groups: Some groups (i.e. AARP, churches, etc.) may allow inserts in mailings, release of their membership list or presentations made at meetings.

4) Mailing lists**:** Database sources (e.g. medical administration departments of hospitals and VA centers, university alumni lists, large corporate employee lists) can be searched for male participants 45 years of age or older who live in the area. A listing of names and addresses can then be generated for mass mailings.

5) Health fairs: Representatives from the clinic attending health fairs can provide information about the study via posters and handouts, as well as potential participants by administering the AUA symptoms score questionnaire and asking about prior BPH intervention.

In general, active strategies that identify a potential pool of eligible participants and recruits will yield larger numbers of eligible participants than passive strategies that consist of informing urology clinics, flyers or brochures in clinics etc.

FORMS REQUIRED FOR RECRUITMENT

CAM103 – CAMUS Weekly Recruitment/Enrollment Report (REVISED 10/09/08)

The CAMUS weekly recruitment/enrollment report was created to capture the enormous amount of effort study site coordinators and PIs put into recruiting participants; it was also designed to help the DCC and the sites identify and replicate successful recruitment strategies.

All fields in the form require numerical values. Please write legibly and enter one number per box.

Field 1: Enter the date for the Friday of the week for which you are submitting the enrollment report.

Field 2: Enter the 3-digit Site number.

Field 3: This field is pre-filled.

Fields 4-12: For each type of recruitment activity, enter the following –

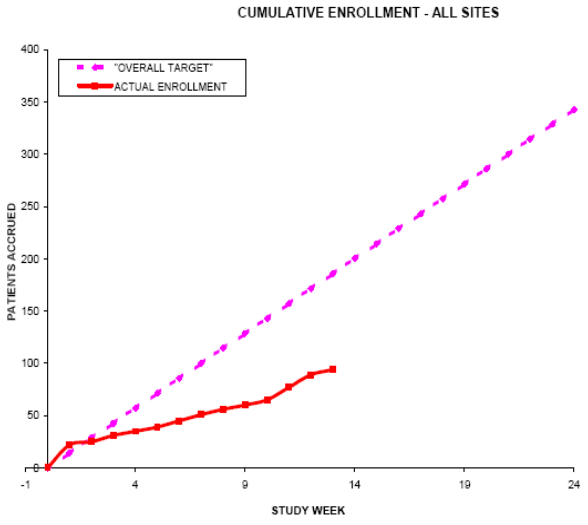
- The number of each activity (fliers posted, radio spots, TV spots, newspaper ads, etc.) during the week.
- The number of contacts generated.
- The number of men who were contacted and consented to participate in the study.
- The number of SV1 visits scheduled.
- The number of eligible participants resulting from the SV1 visits.
- The number of SV2 visits scheduled.
- The number of randomizations.
- Yield – number randomized / number of contacts.

RECRUITMENT REPORTS

The DCC will provide all the sites with weekly recruitment reports. The reports will consist of a graph that compares target recruitment to actual recruitment as well a table that provides the recruitment information for the current week and week before for each site. The table will also provide estimates of both the number of weeks it will take to complete enrollment and the number of patients that can be recruited in the allotted recruitment period given the current rate of recruitment. Examples of the graph and table are provided below.

Week	13	CAMUS Recruiting Status Report					8/30/2008 Projections			
		Current Status					Total recruited in 24 weeks		No of weeks to reach target	
Clinic	Site	Total by last week [1]	New this week [2]	Total to date	Target [3]	Δ [4]	Rate last week	Rate to date	Rate last week	Rate to date
1 CNU	269	17	1	18	17	-1	29	33	24	23
2 NAU	270	5	0	5	17	12	5	9	83	83
3 UIC	271	13	0	13	17	4	13	24	32	32
4 NCK	272	5	1	6	17	11	17	11	83	69
5 NWU	273	6	1	7	17	10	18	13	69	59
6 UCO	274	0	0	0	17	17	0	0	NA	NA
7 UMD	275	6	1	7	17	10	18	13	69	59
8 NYU	276	5	0	5	17	12	5	9	83	83
9 ONU	277	9	0	9	17	8	9	17	46	46
10 YLU	278	18	0	18	17	-1	18	33	23	23
11 TXU	279	5	1	6	17	11	17	11	83	69
	All Sites	89	5	94	186	92	149	174	51	48

[1] The number of weeks alloted for recruitment is 24
[2] The target per week per clinical site is 1.3
[3] The overall target is 32 per clinical site or 350 for the entire study
[4] Δ=Target - Total to Date
NA = Since no patients were recruited there is no rate that can be applied.



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Assigning Screening Numbers to Participants
At the first screening visit, the clinical site will assign each participant a 7-string screening number that will consist of the 3-digit site number, the letter S, and a 3-digit number beginning with 101 and continuing consecutively for each participant at that site. Thus, the screening number format will be XXXSZZZ where XXX is the site number and ZZZ is the next consecutively numbered participant beginning with 101. Site numbers are given below:

Site Numbers	Site Name
269	Cornell University, Weill Medical College
276	New York University
272	Northern California, Kaiser Permanente
273	Northwestern University
277	Queen's University
274	University of Colorado
271	University of Iowa
275	University of Maryland
279	University of Texas – Southwestern
270	Washington University
278	Yale University

Example: The first participant screened at Cornell University, Weill College of Medicine will be 269S101.

CAM102 – Screening Log Form SV1 (REVISED 10/10/08)
The following information must be recorded for each screened participant:

Field 1: This field is pre-filled.

Field 2: Enter the Participant ID.

Field 3: Enter the date (month, day, and year).

Field 4: Enter the participant's age.

Field 5: Enter the 3-digit site number.

Field 6: Enter the initials of the staff person completing the form.

Fields 7-8: Collect demographic information based on participant self-report. Indicate unknown/not reported if applicable.

Field 9: After Screening Visit 1 (SV1.0), indicate the screening outcome.

Field 10: Indicate the reason for ineligibility if applicable.

CAM102 – Screening Log Form SV2/Baseline (REVISED 10/13/08)

Field 1: This field is pre-filled.

Field 2: Enter the Participant ID.

Field 3: Enter the date (month, day, and year).

Field 4: Enter the participant's age.

Field 5: Enter the 3-digit site number.

Field 6: Enter the initials of the staff person completing the form.

Fields 7-8: Collect demographic information based on participant self-report. Indicate unknown/not reported if applicable.

Field 9: After Screening Visit 2/Baseline, indicate the screening outcome.

Field 10: Indicate the reason for ineligibility if applicable.

Field 11: Indicate if randomized.

Field 12: If randomized, record the Med Kit number assigned. The Med Kit number is provided to you once you have been through the web based randomization.

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CAMUS Clinical Trial
Screening Log Form (CAM102)
SV1

Page Number
1. 1

2. * ParticipantId [ ][ ][ ]S[ ][ ][ ] 3. Date [ ][ ] / [ ][ ] / [ ][ ][ ][ ] 4. Age [ ][ ] 5. Site# [ ][ ][ ] 6. Staff ID [ ][ ]

** This ID# should be used throughout the study any time a participant is screened and eligible for enrollment.*

Circle the appropriate number

	Yes	No	Unknown/Not Reported
7. Ethnicity (Hispanic or Latino)	1	2	3

8. Race (Check all that apply)

- [ ] American Indian or Alaska Native
- [ ] Asian
- [ ] Native Hawaiian or Other Pacific Islander
- [ ] Black or African-American
- [ ] White
- [ ] Unknown or Not Reported

Circle the appropriate number

	Eligible, enrolled	Eligible, but did not enroll	Ineligible
9. Screening Outcome	1	2	3

10. If not eligible, specify _____

Instructions: Please fax to the CAMUS Data Coordinating Center within 24 hours.

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CAMUS Clinical Trial
Screening Log Form (CAM102)
SV2 / Baseline

Page Number
1. 1

* ParticipantId	Date	Age	Site#	Staff ID
2. S	3. / /	4.	5.	6.

** This ID# should be used throughout the study any time a participant is screened and eligible for enrollment.*

Circle the appropriate number

	Yes	No	Unknown/Not Reported
7. Ethnicity (Hispanic or Latino)	1	2	3

8. Race (Check all that apply)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Black or African-American
- ☐ White
- ☐ Unknown or Not Reported

Circle the appropriate number

	Eligible, enrolled	Eligible, but did not enroll	Ineligible
9. Screening Outcome	1	2	3

10. If not eligible, specify _____

	Yes	No
11. Randomized	1	2

12. If, available, please provide the Med Kit # assigned

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Instructions: Please fax to the CAMUS Data Coordinating Center within 24 hours.

VISIT 1 (SV 1.0)

The consent form must be signed by the participant prior to screening. Once the patient has consented, he can be scheduled for the first screening visit. The first screening visit will help determine the patient's eligibility to be randomized to the study.

FORMS REQUIRED FOR SV1.0

CAM Form	Procedure	Completed By
21	Medical History	Study Coordinator
23/24	Assessment of Medicine	Study Coordinator
31	Vital Signs	Study Coordinator
32	Physical and DRE	Principal Investigator
41	PSA	Study Coordinator
42	Uroflow Measurement	Study Coordinator
45	Hematology and EKG	Study Coordinator
46	Urinalysis	Study Coordinator
47	Serum for Banking	Study Coordinator
75	International Prostate Symptom Score (IPSS)	Participant

The Study Site Coordinator should have a folder containing all the forms required for the SV1.0 printed and ready for the visit. All of the forms for this visit are to be completed by the Coordinator. **If the patient is being re-screened, you will need the dates of the previous screening. Maintaining a folder for each patient could facilitate the accessibility of information.**

CAM21 – Demographic Data and Medical History Form (REVISED 10/10/08)

This six-page form records information about the patient's medical history.

Fields to be completed:

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly. The Participant ID is required on each page to enable the DCC to identify the participant to which the page belongs in case the order of the forms is lost in transit between the clinical site and the DCC or forms for multiple participants are combined.

Question 1: Enter the date of the visit (month, day and year).

Question 2: Enter the Participant ID.

Question 3: The page number is pre-filled.

Question 4: Enter the 3-digit Site #.

Question 5: Enter the initials of the staff person completing the form.

Question 6: Enter the date (month, day and year) the consent form was signed. **EXCLUDE if no signed consent form.**

Question 7: EXCLUDE if enrolled in another treatment trial for any disease in the 30 days before screening visit 1.

Question 8: If this is the first screening check "Initial screen". If the patient was screened before check "Rescreen" and enter the month, day and year of the first screening. Also enter the number of attempted screenings (including the current one).

Section A: Demographics and Social Characteristics

Questions 9-12: Collect general demographic information. If the patient does not know or refuses to answer, check or circle the appropriate response.

Section B: Concomitant Medications

Question 13: Serves as a guide to complete the forms that record concomitant medications that the patient maybe taking.

If the patient is on medications that are not related to urological conditions, please complete form CAM 23.

If the patient is on medications related to urological conditions please complete form CAM 24.

If the patient is on medications that are not related to urological conditions **and** medications related to urological conditions please complete both CAM 23 and CAM 24.

For the SV1.0 the information required is any medication that the patient has been on for the last six months; you will need

a) The generic names of the medication
b) Total dosage (?)
c) Frequency of dose

d) Mode of administration
e) Date medication started
f) Date medication stopped

Since the number of pages required for these forms will vary with the patient, page numbers have been omitted from these headers. Please be sure to fill in the page number along with other header information.

Do not duplicate medications listed in CAM 23 on CAM 24 (the Urology Medication Tracking Form).

Section C: Medical History

Questions 14-35: Collect information on existing medical conditions. If the patient does not know, circle number 3.

Section D: Family History

Questions 36-37: Record information about patient's family history of BPH and / or Prostate Cancer. Make sure that the information provided is only about blood relations.

Section E: BPH Symptoms

Questions 38-40: Record information about past / current symptoms of BPH.

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CAMUS Clinical Trial
Demographic Data and Medical History Form (CAM21)

1. Visit Date: ___/___/____ (mm/dd/yyyy)
2. Participant ID: ____S____
3. Page Number: 1
4. Site#: ____
5. Staff ID: ____

Instruction: The study coordinator or investigator administers this form with the participant in a face-to-face interview. Eligibility criteria are noted throughout the form next to the pertinent items (indicated by the item number in a box). Screening stops when the participant first fails an eligibility criterion.

Circle the appropriate number

6. Date consent form signed: ___/___/____ (mm/dd/yyyy)
Excluded if no signed consent form.

	Yes	No
7. Were you enrolled in another treatment trial for any disease in the past 30 days? *Excluded if enrolled in another treatment trial for any disease in the 30 days before screening visit 1.*	1	2

8. Is this an initial screening or a rescreening (check one)?

☐ Initial Screen

☐ Rescreen ⇨ If rescreen, Date of the first screening: ___/___/____ (mm/dd/yyyy)

Number attempted screenings (including the current one) ____

A. Demographics and Social Characteristics

9. What is your year of birth? ____ (yyyy) *Excluded if < 45 years old.*

10. Race / Ethnicity	Yes	No	Unknown (Individuals not reporting ethnicity)
(a) Do you consider yourself Hispanic or Latino?	1	2	3

(b) Race: **Check all that apply.** To probe race, for each category (except Unknown or Not Reported) ask "Are you...?" and check the box if the participant responds "yes". Check the Unknown or Not Reported category if the participant responds "no" to all other categories or does not want answer the race question.

☐ American Indian or Alaska Native
☐ Black or African-American
☐ Asian
☐ White
☐ Native Hawaiian or Other Pacific Islander
☐ Unknown or Not Reported

	Yes	No	Don't want to respond
11. Are you married or in a long-term committed relationship?	1	2	9

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CAMUS Clinical Trial
Demographic Data and Medical History Form (CAM21)

Participant ID
2. | | | | S | | | |

Page Number
3. 2

12. What is the highest educational level that you achieved (check one)?

- ☐ (1)Less than high school graduate
- ☐ (2)High school graduate
- ☐ (3)Some college or technical school beyond high school
- ☐ (4)College or technical school graduate
- ☐ (5)Post-college coursework or degree
- ☐ (9)Don't want to respond

B. Concomitant Medications

	Yes	No
13. Do you take any medication on a regular basis?	1	2

If "Yes", fill out form CAM23(Concomitant Medication form) and CAM24(Urology Medication Tracking form).

Excluded if :
1. *On an alpha-blocker within one month prior to the first screening visit OR*
2. *Phytotherapy or 5-alpha reductase inhibitor for BPH within 3 months prior to the first screening visit OR*
3. *Taken phenylephrine, pseudoephedrine, tricyclic antidepressants, an anticholinergic or cholinergic medication within 4 weeks of the first screening visit (Except topical anticholinergic eye drops used for glaucoma more than 1 month prior to the screening visit 1 or inhaled anticholinergics for COPD) OR*
4. *Taken estrogen, androgen, or any drug producing androgen suppression, or anabolic steroids within 6 months prior to the first screening visit*

C. Medical History

In general, ask , "Has a physician ever told you that you have ..."In some instances you may need to ask, "Do you have..."or "Have you had ..." (e.g., vasectomy).

	Yes	No	Don't Know
14. Congenital disease. *Probe with*: Were you born with a birth defect or an unusual condition such as malformation of the limbs, head, skin, or internal organs?	1	2	3
15. Lung disease. *Probe with*: Have you ever had chronic obstructive pulmonary disorder (COPD), emphysema, asthma, chronic bronchitis, pneumonia, or water on the lungs?	1	2	3
16. Kidney disease. *Probe with*: Do you have kidney or bladder, stones, or kidney problems?	1	2	3
17. Immune disease. *Probe with*: Do you have rheumatoid arthritis or lupus?	1	2	3

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CAMUS Clinical Trial
Demographic Data and Medical History Form (CAM21)

2. Participant ID [ ][ ][ ]S[ ][ ][ ]

Page Number
3. 3

	Yes	No	Don't Know
18. Diabetes. *Probe with*: Do you have diabetes, whether you take medication for it or not?	1	2	3
If yes: a. How long have you had diabetes? [ ][ ].[ ] years			
b. Type of diabetes: Non-insulin dependent 1; Insulin dependent 2; Don't want to respond 9			
c. Have you taken any oral agents for diabetes? Yes 1; No 2			
19. Endocrine disorder. *Probe with*: Do you have a pituitary, thyroid, or adrenal gland disorder, or low testosterone?	1	2	3
20. Liver disease. *Probe with*: Do you have hepatitis or cirrhosis?	1	2	3
21. Gastrointestinal disease. *Probe with*: Do you have ulcers, serious heartburn, gastrointestinal bleeding, gallstones or other problems with your gallbladder, hemorrhoids, polyps, Crohn's disease or ulcerative colitis, diverticulitis, or pancreatitis?	1	2	3
22. Skin disease. *Probe with*: Do you have psoriasis, chronic rash, or eczema?	1	2	3
23. Disease of the nervous system. *Probe with*: Do you have seizures, multiple sclerosis, Parkinson's, stroke, or muscle disease?	1	2	3
Excluded if known primary neurologic conditions such as multiple sclerosis or Parkinson's disease, or other neurological diseases known to affect bladder function.			
24. Cancer. *Probe with:* Do you have or have you had any cancer or carcinoma?	1	2	3
Excluded if history or current evidence of carcinoma of the prostate or bladder, or cancer that is not considered cured, except basal cell or squamous cell carcinoma of the skin (cured defined as no evidence of cancer within the past 5 years).			

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CAMUS Clinical Trial
Demographic Data and Medical History Form (CAM21)

Participant ID
2. [ ][ ][ ]S[ ][ ][ ]

Page Number
3. 4

	Yes	No	Don't Know
25. Anemia. *Probe with:* Do you have anemia?	1	2	3
26. Blood disease other than anemia. *Probe with* : Do you have sickle cell, leukemia, or a bleeding disorder?	1	2	3
27. History of urinary tract infections. *Probe with* : Do you have any of the following urinary conditions: burning, frequency, urgency, hematuria, or bladder spasm?	1	2	3

Excluded if
1. Active urinary tract infection or has undergone cystoscopy or biopsy of the prostate within one month prior to screening visit 1 OR
2. Two documented UTIs of any type in the past year.

28. History of urinary retention. *Probe with* : Have you ever had an inability to urinate at all?	1	2	3
29. Prior history of gross or microscopic hematuria. *Probe with* : Have you ever had visible or microscopic blood in your urine?	1	2	3
30. Prior biopsy of prostate. *Probe with:* Have you previously had a biopsy of your prostate?	1	2	3

If yes, what was the date of your prostate biopsy?

[ ][ ]/ [ ][ ]/ [ ][ ][ ][ ] *Excluded if biopsy of the prostate within the past 4 weeks.*
mm dd yyyy

31. Vasectomy. *Probe with:* Have you had a vasectomy?	1	2	3

If yes, what was the year? [ ][ ][ ][ ]
yyyy

32. History or current evidence of urethral stricture. *Probe with*: Do you currently or have you had a history of urethral stricture?	1	2	3

Excluded if participant has history or current evidence of urethral stricture.

33. Impotence. *Probe with:* Do you have any difficulty with erectile function?	1	2	3
34. Other genitourinary disease. *Probe with:* Do you have incontinence?	1	2	3

If yes, specify ⇨ _____

Excluded if
1. History or current evidence of pelvic radiation or surgery OR
2. Bacterial prostatitis within the past year OR
3. Daily use of a pad or device for incontinence required or a baseline ICSmaleIS score > 14 at baseline.

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CAMUS Clinical Trial
Demographic Data and Medical History Form (CAM21)

Participant ID
2. [ ][ ][ ]S[ ][ ][ ]

Page Number
3. 5

	Yes	No	Don't Know
35. Infectious disease. *Probe with:* Do you have any infectious diseases such as HIV, herpes, or tuberculosis?	1	2	3

D. Family History (blood relations only)

	Yes	No	Don't Know
36. Has anyone in your family been told by a physician that he has BPH?	1	2	3

⇨ If Yes, Check all that apply:

- ☐ (1) Father
- ☐ (1) Two or more brothers
- ☐ (1) Maternal grandfather
- ☐ (1) Paternal grandfather
- ☐ (1) One maternal uncle
- ☐ (1) One paternal uncle
- ☐ (1) Two or more maternal uncles
- ☐ (1) Two or more paternal uncles
- ☐ (1) One brother
- ☐ (1) Other male relative

	Yes	No	Don't Know
37. Has anyone in your family been told by a physician that he has prostate cancer?	1	2	3

⇨ If Yes, Check all that apply:

- ☐ (1) Father
- ☐ (1) Two or more brothers
- ☐ (1) Maternal grandfather
- ☐ (1) Paternal grandfather
- ☐ (1) One maternal uncle
- ☐ (1) One paternal uncle
- ☐ (1) Two or more maternal uncles
- ☐ (1) Two or more paternal uncles
- ☐ (1) One brother
- ☐ (1) Other male relative

E. BPH Symptoms

38. How long have you had symptoms of BPH? ☐☐.☐ years

	Improved	Stabilized	Worsened
39. Would you say that over the past year your symptoms have ...	1	2	3

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CAMUS Clinical Trial
Demographic Data and Medical History Form (CAM21)

Participant ID
2. [ ][ ][ ]S[ ][ ][ ]

Page Number
3. 6

	Yes	No	Don't Know
40. Have you seen a physician or primary care provider within the past 5 years about BPH symptoms?	1	2	3
If yes, what was...: ⇨ check all that apply in (a) - (d):			
(a) Watchful waiting	1	2	3
(b) TURP or other surgical procedure	1	2	3
Excluded if any prior surgical intervention for BPH.			
(c) Prescription Medication	1	2	3
c1. Alpha-blocker	1	2	3
If Yes, alpha-blocker last taken: [ ][ ]/[ ][ ]/[ ][ ][ ][ ] (mm/dd/yyyy)			
Excluded if on alpha-blocker within one month prior to the first screening visit.			
c2. 5-alpha reductase inhibitor	1	2	3
If Yes,5-alpha reductase inhibitor last taken (e.g.finasteride): [ ][ ]/[ ][ ]/[ ][ ][ ][ ] (mm/dd/yyyy)			
Excluded if on 5-alpha reductase inhibitor within 3 months prior to the first screening visit.			
(d) Phytotherapy	1	2	3
If Yes, phytotherapy last taken: [ ][ ]/[ ][ ]/[ ][ ][ ][ ] (mm/dd/yyyy)			
Excluded if on phytotherapy within 3 months prior to the first screening visit.			

CAM 32 – Physical and Digital Rectal Exam Form (REVISED 10/10/08)

If it is not possible to schedule a physical at the SV1.0, this exam may be postponed to the second screening visit (SV2.0).

The physical exam is to be performed by the PI in the protocol of the clinical site. **The form is to be completed by the PI at the site.**

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a physical examination was performed. If yes, complete questions 8-19.

Fields 8-18: All body systems should be examined and any abnormalities noted.

Field 19: Record the prostate size. Circle the appropriate number indicating nodules or indurations, asymmetry, suspicious for cancer, and tenderness.

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CAMUS Clinical Trial
Physical and Digital Rectal Exam Form (CAM32)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

Circle the appropriate number	Yes	No	
7. Was a physical examination done at this visit?	1	2	⇨ If "No", stop here. If "Yes", record below.

	Normal	Abnormal	⇨ If abnormal, specify
8. Head, ears, nose, throat	1	2	⇨ _____
9. Eyes	1	2	⇨ _____
10. Neck (include bruits)	1	2	⇨ _____
11. Heart	1	2	⇨ _____
12. Lungs and respiration	1	2	⇨ _____
13. Abdomen (include bruits)	1	2	⇨ _____
14. Liver	1	2	⇨ _____
15. Musculoskeletal	1	2	⇨ _____
16. Skin	1	2	⇨ _____
17. Neurological	1	2	⇨ _____

Excluded at screening visit 1 if known primary neurologic conditions such as multiple sclerosis or Parkinson's disease, or any other neurological diseases known to affect bladder function.

	Normal	Abnormal	⇨ If abnormal, specify
18. Urogenital	1	2	⇨ _____

Excluded at screening visit 1 if daily use of a pad or device for incontinence required, or a baseline ICSmaleIS score > 14.

19. Digital Rectal Examination (DRE) performed by a physician:

(a) Prostate size: ☐☐☐ gm

Circle the appropriate number	Yes	No	Don't Know
(b) Nodules or indurations:	1	2	3
(c) Asymmetry:	1	2	3
(d) Suspicious for cancer:	1	2	3
(e) Tenderness:	1	2	3

Excluded at screening visit 1 if history or current evidence of carcinoma of the prostate or bladder.

CAM 31 – Vital Signs Form (REVISED 10/10/08)

The old forms for this study ask for the BP to be taken both lying down and standing.

For this study, you only need to take two consecutive measurements five minutes apart, both sitting down

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the 3-digit site number.

Field 4: This field is pre-filled.

Field 5: Enter the visit number. Refer to the table.

Field 6: Enter the initials of the staff person completing the form.

Field 7: Check the appropriate visit type.

The vital signs have to be recorded at the first screening visit or the second visit.

Field 8: Indicate whether or not vital signs were obtained. If yes, complete questions 9-11.

Draft

CAMUS Clinical Trial
Vital Signs Form (CAM31)

Visit Date 1. ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)

2. Participant ID ☐☐☐S☐☐☐

3. Site# ☐☐☐

Page Number 4. 1

Visit Number 5. ☐☐

01=SV1.0	04=Week 4	28=Week 28	52=Week 52
02=SV2.0	12=Week 12	36=Week 36	60=Week 60
	24=Week 24	48=Week 48	72=Week 72

Staff ID 6. ☐☐

Visit type
7. ☐ In-Clinic Visit
☐ Telephone Interview

Circle the appropriate number	Yes	No
8. Were vital signs done at this visit? ⇨ **If "No", stop here. If "Yes", record below.**	1	2

9. Height: ☐☐ inches (In-Clinic Only)

10. Weight: ☐☐☐ pounds (In-Clinic Only)

11. Seated measurements (reading 1 taken immediately, reading 2 taken 1 minute later):

(a) Blood pressure reading 1 ☐☐☐ (Systolic) / ☐☐☐ (Diastolic) mm Hg

(b) Heart rate reading 1 ☐☐☐ bpm

(c) Time of Day 1 ☐☐☐☐ ☐ AM ☐ PM

(d) Blood pressure reading 2 ☐☐☐ (Systolic) / ☐☐☐ (Diastolic) mm Hg

(e) Heart rate reading 2 ☐☐☐ bpm

CAM23 – Concomitant Medication Form (REVISED 10/13/08)

Two separate medications can be reported on one form. For additional medications, please use an additional CAM23 and enter the page number in field 3.

Since the number of pages required for these forms will vary with the patient, page numbers have been omitted from these headers. Please be sure to fill in the page number along with other header information.

Do not duplicate medications listed on the Urology Medication Tracking Form (CAM 24).

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: If SV1, indicate whether or not the participant has taken any medications during the last 6 months. If this is not SV1, indicate whether or not the participant has started or stopped any urology medications since the last visit. **If yes, complete fields 8-23.**

Field 8: Enter the generic name of the medication.

Field 9: Enter the total dosage.

Field 10: Enter the dosage units. Refer to the dosage unit codes at the bottom of the form.

Field 11: Enter the frequency of dose. Refer to the frequency codes at the bottom of the form.

Field 12: Enter the mode of administration. Refer to the mode of administration codes at the bottom of the form.

Field 13: Enter the date the medication was started.

Field 14: Enter the date the medication was stopped **OR** check “Ongoing”.

Field 15: Indicate the primary reason for use or change.

Draft

CAMUS Clinical Trial
Concomitant Medication Form (CAM23)

1. Visit Date ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)
2. Participant ID ☐☐☐S☐☐☐
3. Page Number ☐
4. Visit Number ☐☐

01=SV1.0	04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

5. Site# ☐☐☐
6. Staff ID ☐☐

Do not duplicate medications listed on the Urology Medication Tracking Form (CAM24). Number page(s) in upper right corner of the form.

Circle the appropriate number

	Yes	No	Don't Know
	1	2	3

7. If this is screening visit 1, has the participant taken any medications during the last 6 months? If this is not screening visit 1, since the last visit, has the participant started or stopped any medications ?
   ⇨ **If "Yes", continue to complete below.**
   ⇨ **If "No", stop here.**

8. **Medication** *(Give generic name):* _____

9. **Total Dosage:** _____
10. **Dosage Units** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

11. **Frequency** ☐ *(See Codes below)* ⇨ If "other", Specify: _____
12. **Mode of Administration** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

13. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐
Ongoing: ☐ *Or* ⇨
14. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

15. **Primary Reason for Use or Change:** _____

16. **Medication** *(Give generic name):* _____

17. **Total Dosage:** _____
18. **Dosage Units** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

19. **Frequency** ☐ *(See Codes below)* ⇨ If "other", Specify: _____
20. **Mode of Administration** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

21. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐
Ongoing: ☐ *Or* ⇨
22. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

23. **Primary Reason for Use or Change:** _____

Dosage Units Codes: (1) mg, (2) mcg or ug, (3) ml or cc, (4) units, (5) g, (6) Other (specify)

Frequency Codes: (1) Single Dose, (2) BID, (3) TID, (4) QID, (5) PRN, (6) Q4h, (7) Other (specify)

Mode of Administration Codes: (1) Intravenous, (2) Oral, (3) Intra-muscular, (4) Sub-lingual, (5) Intra-urethral, (6) Patches, (7) Other (specify)

For Official use only

October 13, 2008 CAM23 RS

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

CAM24 – Urology Medication Tracking Form (REVISED 10/13/08)

Two separate medications can be reported on one form. For additional medications, please use an additional CAM24 and enter the page number in field 3.

Since the number of pages required for these forms will vary with the patient, page numbers have been omitted from these headers. Please be sure to fill in the page number along with other header information.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: If SV1, indicate whether or not the participant has taken any urology medications during the last 6 months. If this is not SV1, indicate whether or not the participant has started or stopped any urology medications since the last visit. **If yes, complete fields 8-21.**

Field 8: Enter the generic name of the medication.

Field 9: Enter the total dosage.

Field 10: Enter the dosage units. Refer to the dosage unit codes at the bottom of the form.

Field 11: Enter the frequency of dose. Refer to the frequency codes at the bottom of the form.

Field 12: Enter the mode of administration. Refer to the mode of administration codes at the bottom of the form.

Field 13: Enter the date the medication was started.

Field 14: Enter the date the medication was stopped **OR** check “Ongoing”.

Draft

CAMUS Clinical Trial
Urology Medication Tracking Form (CAM24)

1. Visit Date ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID ☐☐☐S☐☐☐
3. Page Number ☐
4. Visit Number ☐☐

01=SV1.0	04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

5. Site# ☐☐☐
6. Staff ID ☐☐

Do not duplicate medications listed on the Concomitant Medication Form (CAM23). Number page(s) in upper right corner of the form.

Circle the appropriate number

	Yes	No	Don't Know
7. If this is screening visit 1, has the participant taken any urology medications during the last 6 months? If this is not screening visit 1, since the last visit, has the participant started or stopped any urology medications?	1	2	3

⇨ **If "Yes", continue to complete below.**

⇨ **If "No", stop here.**

8. **Medication** *(Give generic name):* _____

9. **Total Dosage:** _____

10. **Dosage Units** ☐ ⇨ If "other", Specify: _____
(See Codes below)

11. **Frequency** ☐ ⇨ If "other", Specify: _____
(See Codes below)

12. **Mode of Administration** ☐ ⇨ If "other", Specify: _____
(See Codes below)

13. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

Ongoing: ☐ *Or* ⇨

14. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

15. **Medication** *(Give generic name):* _____

16. **Total Dosage:** _____

17. **Dosage Units** ☐ ⇨ If "other", Specify: _____
(See Codes below)

18. **Frequency** ☐ ⇨ If "other", Specify: _____
(See Codes below)

19. **Mode of Administration** ☐ ⇨ If "other", Specify: _____
(See Codes below)

20. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

Ongoing: ☐ *Or* ⇨

21. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

Dosage Units Codes: **(1)** mg, **(2)** mcg or ug, **(3)** ml or cc, **(4)** units, **(5)** g, **(6)** Other (specify)

Frequency Codes: **(1)** Single Dose, **(2)** BID, **(3)** TID, **(4)** QID, **(5)** PRN, **(6)** Q4h, **(7)** Other (specify)

Mode of Administration Codes: **(1)** Intravenous, **(2)** Oral, (3) Intra-muscular, **(4)** Sub-lingual, **(5)** Intra-urethral, **(6)** Patches, **(7)** Other (specify)

For Official use only

October 13, 2008 CAM24 RS

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

CAM41 – PSA Sample Collection (REVISED 10/10/08)

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

A PSA level above 10ng/ml is an exclusionary criterion.

All PSA levels for the study are done at the same laboratory. The blood sample has to be collected and sent to the laboratory as set forth in the section on sample collection.

When the PSA level comes back, it is recorded on this same form.

In the old forms where there is only one decimal place, please just record the first number after the decimal. **There is no need to round up or down**.

Field 7: Indicate whether or not a serum PSA sample was collected. If yes, record the date of collection and complete fields 8-10.

Field 8: Indicate whether or not the serum PSA sample was shipped to central lab.

Field 9: Record the date of shipment.

Field 10: Record the PSA results.

Draft

CAMUS Clinical Trial
PSA Sample Collection (CAM41)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0; 24=Week 24, 48=Week 48, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

Circle the appropriate number

Serum PSA:	**Yes**	**No**
7. Was a serum PSA sample collected at this visit?	1	2

⇨ If "Yes", record date of collection. ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

⇨ If "No", STOP.

	Yes	**No**
8. *Was a serum PSA sample shipped to central lab?	1	2

9. *If "Yes", record the date of shipment: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

10. PSA results from Central Lab: ☐☐.☐☐ ng/ml

For screening visit 1, excluded if serum prostate specific antigen level > 10 ng/ml.

**Does not apply to site# 277*

CAM42 – Uroflow Measurement Form (REVISED 10/10/08)

This form records information from the Uroflow tests.

Peak flow rate < 4 ml/sec and voided volume < 125 ml are both exclusionary criteria.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not uroflow measurements were obtained. If yes, complete fields 8-14.

Draft

CAMUS Clinical Trial
Uroflow Measurement Form (CAM42)

Visit Date: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)

2. Participant ID: ☐☐☐S☐☐☐

Page Number 3. 1

Visit Number ☐☐

01=SV1.0 02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

5. Site# ☐☐☐

6. Staff ID ☐☐

Circle the appropriate number	Yes	No
7. Were uroflow measurements done at this visit?	1	2

⇨ **If "No", stop here.**
If "Yes", record below.

8. Voiding time: ☐☐☐ sec

9. Flow time: ☐☐☐ sec

10. Time to maximum flow: ☐☐☐ sec

11. Peak flow rate: ☐☐.☐☐ ml/sec

For screening visits 1 and 2: Excluded if peak flow rate is less than 4 ml/sec.

12. Mean flow rate: ☐☐.☐☐ ml/sec

13. Voided volume: ☐☐☐☐ ml

For screening visits: Excluded if voided volume < 125 ml.

14. Post-void residual: ☐☐☐ ml

CAM45 – CBC, Serum Chemistries, Prothrombin Time and EKG Form (REVISED 10/14/08)

The old forms only ask if the values were normal or abnormal.
The old forms have boxes that you place a mark in.

The new forms record actual values for all the laboratory measures.
The new forms have the codes (1, = yes, 2 = no, 3 = don't know) that should be circled.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a complete blood count was obtained. If yes, complete a-e.

Field 8: Record the prothrombin time.

Field 9: Indicate whether or not a serum chemistry panel was obtained. If yes, complete a-i.

Field 10: For baseline, 24, 48 and 72 week visits, indicate whether or not an EKG was performed.

Recording whether an EKG is normal or abnormal with respect to recent MI or active Ischemia should be based on a Final report from a cardiologist.

All attempts should be made to ensure that these reports are received in a timely manner, so that the second screening visit and randomization visits can be scheduled in a timely fashion.

If any values are abnormal, complete the adverse events form (CAM81).

CAMUS Clinical Trial
CBC, Serum Chemistries, Prothrombin Time and EKG Form (CAM45)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0; 12=Week 12, 24=Week 24; 36=Week 36, 48=Week 48; 60=Week 60, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

Circle the appropriate number

7. Complete blood count:

	Yes	No
Was a complete blood count done at this visit?	1	2

If "No", skip to question 8. If "Yes", record below.

		Normal	Abnormal	Not Done
(a) Leukocyte count (WBC):	☐☐.☐☐ thou/cmm	1	2	3
(b) Erythrocyte count (RBC):	☐☐.☐☐ mill/cmm	1	2	3
(c) Hemoglobin:	☐☐.☐☐ g/dl	1	2	3
(d) Hematocrit:	☐☐.☐☐ %	1	2	3
(e) Platelet count:	☐☐.☐☐ thou/cmm	1	2	3

If any values are abnormal, complete adverse events form (CAM81).

8. Prothrombin time:

☐☐.☐☐ **Seconds** ☐☐.☐☐ **Upper limit of normal or control value (Seconds)** **INR:** ☐.☐☐

9. Serum chemistries:

	Yes	No
Was a serum chemistry panel done at this visit?	1	2

If "No", stop. If "Yes", record below.

		Normal	Abnormal	Not Done
(a) Sodium:	☐☐☐.☐☐ meq/l	1	2	3
(b) Potassium:	☐☐☐.☐☐ meq/l	1	2	3
(c) Chloride:	☐☐☐.☐☐ meq/l	1	2	3
(d) Bicarbonate:	☐☐.☐☐ meq/l	1	2	3
(e) Glucose:	☐☐☐.☐☐ meq/l	1	2	3
(f) Creatinine	☐☐☐.☐☐ meq/l	1	2	3
(g) ALT (SGPT):	☐☐.☐☐ IU/L	1	2	3
(h) AST (SGOT):	☐☐.☐☐ IU/L	1	2	3
(i) GGT:	☐☐.☐☐ IU/L	1	2	3

8. Complete this section every Baseline, 24, 48 and 72 week visit only.

Electrocardiogram:	1	2	3

If any values are abnormal, complete adverse events form (CAM81).

CAM46 – Urinalysis Form (REVISED 10/10/08)

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a urinalysis was performed. If yes, complete fields 8-9

Field 8: Record the results based on the dipstick test.

Field 9: Record the results based on the microscopic urinalysis.

Draft

CAMUS Clinical Trial
Urinalysis Form (CAM46)

Page Number 3. 1

1. Visit Date ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

2. Participant ID ☐☐☐S☐☐☐

4. Visit Number ☐☐ (01=SV1.0, 72=Week 72)

5. Site# ☐☐☐

6. Staff ID ☐☐

Circle the appropriate number	Yes	No
7. Was an urinalysis done at this visit?	1	2

⇨ **If "Yes", record the results below.**

⇨ **If "No", stop.**

(8) Dipstick

(a) pH: ☐.☐

	0	*trace*	*1+*	*2+*	*3+*	*4+*
(b) Glucose	1	2	3	4	5	6
(c) Blood	1	2	3	4	5	6
(d) Ketones	1	2	3	4	5	6
(e) Protein	1	2	3	4	5	6
(f) Leukocyte esterase	1	2	3	4	5	6

(9) If dipstick is positive (> 0) for blood or leukocyte esterase, send specimen for microscopic urinalysis and code results below.

	none, negative, WNL	*1-5, trace, present, slight, rare*	*6-15, moderate*	*16-30, many, frequent*	*>30, innumerable, TNTC*
(a) WBC	1	2	3	4	5
(b) RBC	1	2	3	4	5
(c) Epithelial cells	1	2	3	4	5
(d) Mucous	1	2	3	4	5
(e) Bacteria	1	2	3	4	5
(f) Casts hyaline	1	2	3	4	5
(g) Casts other	1	2	3	4	5

For Official use only

October 10, 2008 CAM46 RS

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

CAM47 – Serum for Banking Form (REVISED 10/10/08)

If the patient has consented to it, a serum sample from the patient collected at the first visit and the separation visit is to be sent to the NIDDK repository. The samples are being collected and stored for future ancillary studies.

This form is used to identify patients whose sample is collected during SV1.0 and sent to the NIDDK.

If no sample is collected, the reasons for not collecting are also recorded.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a serum sample was collected.

Field 8: Enter the date of collection if applicable.

Field 9: Indicate the reason specimens were not obtained if applicable.

Field 10: Indicate whether or not the sample was shipped.

Field 11: Enter the date of shipment if applicable.

[redacted] Draft

CAMUS Clinical Trial
Serum for Banking Form (CAM47)

1. Visit Date: ☐☐ / ☐☐ / ☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

Circle the appropriate number

	Yes	No
7. Was a serum sample collected at this visit?	1	2

8. If "Yes", Date of collection: ☐☐ / ☐☐ / ☐☐☐☐ (mm / dd / yyyy)

9. If specimens were not obtained for CAMUS, please indicate reason (Check only one).

- ☐ (1)Patient refused to give informed consent for CAMUS serum studies (banking).
- ☐ (2)Patient was not asked to consider CAMUS serum studies (banking).
- ☐ (3)Other, specify: _____

	Yes	No
10. Was a serum sample shipped to NIDDK repository?	1	2

11. If "Yes", record the date of shipment: ☐☐ / ☐☐ / ☐☐☐☐ (mm / dd / yyyy)

CAM75 – International Prostate Symptom Score (IPSS) (REVISED 10/09/08)

This form is completed by the participant. The header information should be completed by the study coordinator.

The old forms have boxes that you place a mark in.

The new forms record actual values for all the laboratory measures.
The new forms have the codes (1, = yes, 2 = no, 3 = don't know) that should be circled.

Questions 7-13 assess the degree of discomfort BPH is causing the participant. The answers are scaled from 0 to 5, 0 indicating no discomfort and 5 indicating a lot. The AUA score is calculated by adding the scores of the answers to questions 7-13.

Questions 15 & 16 should also be completed but not included in the score.

The completion of the TPSS form completes all the requirements for the SV1.0.

Please fax completed forms to the DCC. Forms should be faxed in within 3 days of the SV1.0.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-13: These fields are completed by the participant.

Field 14: The study coordinator enters the AUASS.

Fields 15-16: These fields are completed by the participant.

Draft

CAMUS Clinical Trial
International Prostate Symptom Score (IPSS) For (CAM75)
(AUA Symptom Score & IPSS Quality of Life Questions)

1. Visit Date: ___/___/____ (mm / dd / yyyy)
2. Participant ID: ____S___
3. Page Number: 1
4. Visit Number: ___ (01=SV1.0, 02=SV2.0, 12=Week 12, 24=Week 24, 36=Week 36, 48=Week 48, 60=Week 60, 72=Week 72)
5. Site#: ___
6. Staff ID: ___

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number that best describes your condition.*

	not at all	*less than 1 time in 5*	*less than half the time*	*about half the time*	*more than half the time*	*almost always*
7. Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
8. Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5
9. Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
10. Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5
11. Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5
12. Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5
	None	*1 time*	*2 times*	*3 times*	*4 times*	*5 or more times*
13. Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	0	1	2	3	4	5

14. *To be completed by the study coordinator:* *AUASS =* ____ *(Total of items 7-13.)*

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October 9, 2008 CAM75 RS

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Draft

CAMUS Clinical Trial
International Prostate Symptom Score (IPSS) For (CAM75)
(AUA Symptom Score & IPSS Quality of Life Questions)

Participant ID
2. [ ][ ][ ][S][ ][ ][ ]

Page Number
3. 2

Visit Number
4. [ ][ ]

01=SV1.0 02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

	Delighted	*Pleased*	*Mostly satisfied*	*Mixed-about equally satisfied and dissatisfied*	*Mostly dissatisfied*	*Unhappy*	*Terrible*
15. If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	1	2	3	4	5	6	7

	Not at all	*Less than 1 time in 5*	*Less than half the time*	*About half the time*	*More than half the time*	*Almost always*
16. Over the past month, how often when you felt the urge to urinate, did you leak urine before you could get to the toilet?	1	2	3	4	5	6

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Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Visit 2 (SV 2.0)

If the participant successfully satisfies the inclusion/exclusion criteria based on the measurements during SV1.0, he will be scheduled for screening visit #2 (SV2.0).

IMPORTANT NOTES ABOUT SREENING

- **The screening period (from Screening Visit 1 to randomization) should not exceed 6 weeks (42 days).**
- If a participant is not randomized within 6 weeks after Screening Visit 1 (SV1.0), the participant must re-enter the screening period in order to be considered eligible for randomization. **Thus, an eligible participant should return for randomization within 6 weeks of Screening Visit 1**.
- The same screening number must be used when re-screening a participant.
- Randomization can be combined with Screening Visit #2 (SV2.0) for the participant's convenience.

FORMS FOR SV2.0

CAM Form	Procedure	Completed By
31	Vital Signs	Study Coordinator
32	Physical and DRE	Principal Investigator
41	PSA	Study Coordinator
42	Uroflow Measurement	Study Coordinator
45	Hematology and EKG	Study Coordinator
74	Bladder Function	Participant
75	International Prostate Symptom Score (IPSS)	Participant

CAM 31 – Vital Signs Form (REVISED 10/10/08)

The old forms for this study ask for the BP to be taken both lying down and standing.

For this study, you only need to take two consecutive measurements five minutes apart, both sitting down

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the 3-digit site number.

Field 4: This field is pre-filled.

Field 5: Enter the visit number. Refer to the table.

Field 6: Enter the initials of the staff person completing the form.

Field 7: Check the appropriate visit type.

The vital signs have to be recorded at the first screening visit or the second visit.

Field 8: Indicate whether or not vital signs were obtained. If yes, complete questions 9-11.

Draft

CAMUS Clinical Trial
Vital Signs Form (CAM31)

1. Visit Date: ☐☐ / ☐☐ / ☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Site#: ☐☐☐
4. Page Number: 1
5. Visit Number: ☐☐ (01=SV1.0, 02=SV2.0, 04=Week 4, 12=Week 12, 24=Week 24, 28=Week 28, 36=Week 36, 48=Week 48, 52=Week 52, 60=Week 60, 72=Week 72)
6. Staff ID: ☐☐
7. Visit type: ☐ In-Clinic Visit ☐ Telephone Interview

Circle the appropriate number	Yes	No
8. Were vital signs done at this visit? ⇨ If "No", stop here. If "Yes", record below.	1	2

9. Height: ☐☐ inches (In-Clinic Only)

10. Weight: ☐☐☐ pounds (In-Clinic Only)

11. Seated measurements (reading 1 taken immediately, reading 2 taken 1 minute later):

(a) Blood pressure reading 1 ☐☐☐ (Systolic) / ☐☐☐ (Diastolic) mm Hg

(b) Heart rate reading 1 ☐☐☐ bpm

(c) Time of Day 1 ☐☐☐☐ ☐ AM ☐ PM

(d) Blood pressure reading 2 ☐☐☐ (Systolic) / ☐☐☐ (Diastolic) mm Hg

(e) Heart rate reading 2 ☐☐☐ bpm

CAM 32 – Physical and Digital Rectal Exam Form (REVISED 10/10/08)

If it is not possible to schedule a physical at the SV1.0, this exam may be postponed to the second screening visit (SV2.0).

The physical exam is to be performed by the PI in the protocol of the clinical site. **The form is to be completed by the PI at the site.**

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a physical examination was performed. If yes, complete questions 8-19.

Fields 8-18: All body systems should be examined and any abnormalities noted.

Field 19: Record the prostate size. Circle the appropriate number indicating nodules or indurations, asymmetry, suspicious for cancer, and tenderness.

Draft

CAMUS Clinical Trial
Physical and Digital Rectal Exam Form (CAM32)

1. Visit Date: ____ / ____ / ____ (mm / dd / yyyy)
2. Participant ID: ____ S ____
3. Page Number: 1
4. Visit Number: ____ (01=SV1.0, 72=Week 72)
5. Site#: ____
6. Staff ID: ____

Circle the appropriate number	Yes	No	
7. Was a physical examination done at this visit?	1	2	⇨ If "No", stop here. If "Yes", record below.

	Normal	Abnormal	⇨ If abnormal, specify
8. Head, ears, nose, throat	1	2	⇨ _____
9. Eyes	1	2	⇨ _____
10. Neck (include bruits)	1	2	⇨ _____
11. Heart	1	2	⇨ _____
12. Lungs and respiration	1	2	⇨ _____
13. Abdomen (include bruits)	1	2	⇨ _____
14. Liver	1	2	⇨ _____
15. Musculoskeletal	1	2	⇨ _____
16. Skin	1	2	⇨ _____
17. Neurological	1	2	⇨ _____

Excluded at screening visit 1 if known primary neurologic conditions such as multiple sclerosis or Parkinson's disease, or any other neurological diseases known to affect bladder function.

	Normal	Abnormal	⇨ If abnormal, specify
18. Urogenital	1	2	⇨ _____

Excluded at screening visit 1 if daily use of a pad or device for incontinence required, or a baseline ICSmaleIS score > 14.

19. Digital Rectal Examination (DRE) performed by a physician:

(a) Prostate size: ____ gm

Circle the appropriate number	Yes	No	Don't Know
(b) Nodules or indurations:	1	2	3
(c) Asymmetry:	1	2	3
(d) Suspicious for cancer:	1	2	3
(e) Tenderness:	1	2	3

Excluded at screening visit 1 if history or current evidence of carcinoma of the prostate or bladder.

CAM41 – PSA Sample Collection (REVISED 10/10/08)

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

A PSA level above 10ng/ml is an exclusionary criterion.

All PSA levels for the study are done at the same laboratory. The blood sample has to be collected and sent to the laboratory as set forth in the section on sample collection.

When the PSA level comes back, it is recorded on this same form.

In the old forms where there is only one decimal place, please just record the first number after the decimal. **There is no need to round up or down**.

Field 7: Indicate whether or not a serum PSA sample was collected. If yes, record the date of collection and complete fields 8-10.

Field 8: Indicate whether or not the serum PSA sample was shipped to central lab.

Field 9: Record the date of shipment.

Field 10: Record the PSA results.

Draft

CAMUS Clinical Trial
PSA Sample Collection (CAM41)

1. Visit Date: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0; 24=Week 24, 48=Week 48, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

Circle the appropriate number

Serum PSA:

	Yes	No
7. Was a serum PSA sample collected at this visit?	1	2

⇨ If "Yes", record date of collection. ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)

⇨ If "No", STOP.

	Yes	No
8. *Was a serum PSA sample shipped to central lab?	1	2

9. *If "Yes", record the date of shipment: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)

10. PSA results from Central Lab: ☐☐.☐☐ ng/ml

For screening visit 1, excluded if serum prostate specific antigen level > 10 ng/ml.

**Does not apply to site# 277*

CAM42 – Uroflow Measurement Form (REVISED 10/10/08)

This form records information from the Uroflow tests.

Peak flow rate < 4 ml/sec and voided volume < 125 ml are both exclusionary criteria.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not uroflow measurements were obtained. If yes, complete fields 8-14.

Draft

CAMUS Clinical Trial
Uroflow Measurement Form (CAM42)

Visit Date ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)

2. Participant ID ☐☐☐S☐☐☐

Page Number 3. 1

Visit Number ☐☐

01=SV1.0 02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

5. Site# ☐☐☐

6. Staff ID ☐☐

Circle the appropriate number	Yes	No
7. Were uroflow measurements done at this visit?	1	2

⇨ **If "No", stop here.**
If "Yes", record below.

8. Voiding time: ☐☐☐ sec

9. Flow time: ☐☐☐ sec

10. Time to maximum flow: ☐☐☐ sec

11. Peak flow rate: ☐☐.☐☐ ml/sec

For screening visits 1 and 2: Excluded if peak flow rate is less than 4 ml/sec.

12. Mean flow rate: ☐☐.☐☐ ml/sec

13. Voided volume: ☐☐☐☐ ml

For screening visits: Excluded if voided volume < 125 ml.

14. Post-void residual: ☐☐☐ ml

CAM 45 – CBC, Serum Chemistries, Prothrombin Time and EKG Form (REVISED 10/14/08)

The old forms only ask if the values were normal or abnormal.
The old forms have boxes that you place a mark in.

The new forms record actual values for all the laboratory measures.
The new forms have the codes (1, = yes, 2 = no, 3 = don't know) that should be circled.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a complete blood count was obtained. If yes, complete a-e.

Field 8: Record the prothrombin time.

Field 9: Indicate whether or not a serum chemistry panel was obtained. If yes, complete a-i.

Field 10: For baseline, 24, 48 and 72 week visits, indicate whether or not an EKG was performed.

Recording whether an EKG is normal or abnormal with respect to recent MI or active Ischemia should be based on a Final report from a cardiologist.

All attempts should be made to ensure that these reports are received in a timely manner, so that the second screening visit and randomization visits can be scheduled in a timely fashion.

If any values are abnormal, complete the adverse events form (CAM81).

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CAMUS Clinical Trial
CBC, Serum Chemistries, Prothrombin Time and EKG Form (CAM45)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0; 12=Week 12, 24=Week 24; 36=Week 36, 48=Week 48; 60=Week 60, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

Circle the appropriate number

7. Complete blood count:

	Yes	No
Was a complete blood count done at this visit?	1	2

If "No", skip to question 8. If "Yes", record below.

		Normal	Abnormal	Not Done
(a) Leukocyte count (WBC):	☐☐.☐☐ thou/cmm	1	2	3
(b) Erythrocyte count (RBC):	☐☐.☐☐ mill/cmm	1	2	3
(c) Hemoglobin:	☐☐.☐☐ g/dl	1	2	3
(d) Hematocrit:	☐☐.☐☐ %	1	2	3
(e) Platelet count:	☐☐.☐☐ thou/cmm	1	2	3

If any values are abnormal, complete adverse events form (CAM81).

8. Prothrombin time:

☐☐.☐☐ **Seconds** ☐☐.☐☐ **Upper limit of normal or control value (Seconds)** **INR:** ☐.☐☐

9. Serum chemistries:

	Yes	No
Was a serum chemistry panel done at this visit?	1	2

If "No", stop. If "Yes", record below.

		Normal	Abnormal	Not Done
(a) Sodium:	☐☐☐.☐☐ meq/l	1	2	3
(b) Potassium:	☐☐☐.☐☐ meq/l	1	2	3
(c) Chloride:	☐☐☐.☐☐ meq/l	1	2	3
(d) Bicarbonate:	☐☐.☐☐ meq/l	1	2	3
(e) Glucose:	☐☐☐.☐☐ meq/l	1	2	3
(f) Creatinine	☐☐☐.☐☐ meq/l	1	2	3
(g) ALT (SGPT):	☐☐.☐☐ IU/L	1	2	3
(h) AST (SGOT):	☐☐.☐☐ IU/L	1	2	3
(i) GGT:	☐☐.☐☐ IU/L	1	2	3

8. Complete this section every Baseline, 24, 48 and 72 week visit only.

Electrocardiogram:	1	2	3

If any values are abnormal, complete adverse events form (CAM81).

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October 13, 2008 CAM45 RS

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

CAM74 – Bladder Function Form (REVISED 10/09/08)

The CAM74S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6 AND field 13.

The participant completes fields 7-12 AND field 14.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-12: The participant completes these fields.

Field 13: The Study Coordinator calculates the ICSmaleIS Score.

Field 14: The participant completes this field.

Draft

CAMUS Clinical Trial
Bladder Function Form (CAM74)

Visit Date ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)

Participant ID 2. ☐☐☐S☐☐☐

Page Number 3. 1

4. Visit Number ☐☐ — 02=SV2.0 | 12=Week 12, 24=Week 24 | 36=Week 36, 48=Week 48 | 60=Week 60, 72=Week 72

5. Site# ☐☐☐

6. Staff ID ☐☐

This form is completed by the participant.

Instructions: *We would like to find out about your urinary symptoms and we are very grateful that you can help us by filling in this questionnaire. For each question, circle the appropriate number that best describes your condition. Please answer each question, thinking about the symptoms you have experienced in the last month. You will see that some questions ask how often you have a symptom:*

Occasionally = less than one third of the time
Sometimes = between one and two thirds of the time
Most of the time = more than two thirds of the time

In the past month how often:	Never	Occasionally	Sometimes	Most of the time	All of the time
7. Did you have to rush to the toilet to urinate?	0	1	2	3	4
8. Did urine leak before you could get to the toilet?	0	1	2	3	4
9. Did urine leak when you coughed or sneezed?	0	1	2	3	4
10. Did you leak for no obvious reason and without feeling that you wanted to go?	0	1	2	3	4
11. Did you leak urine when you were asleep?	0	1	2	3	4
12. Did you have a slight wetting of your pants a few minutes after you had finished urinating?	0	1	2	3	4

13. *To be completed by the study coordinator:* *ICSmaleIS Score =* ☐☐☐☐ *(Total of items 7-12.)*

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October 9, 2008 CAM74 RS

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Draft

CAMUS Clinical Trial
Bladder Function Form (CAM74)

Participant ID
2. [ ][ ][ ]S[ ][ ][ ]

Page Number
3. 2

Visit Number
4. [ ][ ]

02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

	Very dissatisfied	Moderately dissatisfied	About equally satisfied and dissatisfied	Moderately satisfied	Very satisfied
14. If you had to spend the rest of your life with your urinary or bladder function just the way it is now, how would you feel about that?	1	2	3	4	5

CAM75 – International Prostate Symptom Score (IPSS) (REVISED 10/09/08)

This form is completed by the participant. The header information should be completed by the study coordinator.

The old forms have boxes that you place a mark in.

The new forms record actual values for all the laboratory measures.
The new forms have the codes (1, = yes, 2 = no, 3 = don't know) that should be circled.

Questions 7-13 assess the degree of discomfort BPH is causing the participant. The answers are scaled from 0 to 5, 0 indicating no discomfort and 5 indicating a lot. The AUA score is calculated by adding the scores of the answers to questions 7-13.

Questions 15 & 16 should also be completed but not included in the score.

The completion of the TPSS form completes all the requirements for the SV1.0.

Please fax completed forms to the DCC. Forms should be faxed in within 3 days of the SV1.0.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-13: These fields are completed by the participant.

Field 14: The study coordinator enters the AUASS.

Fields 15-16: These fields are completed by the participant.

Draft

CAMUS Clinical Trial
International Prostate Symptom Score (IPSS) For (CAM75)
(AUA Symptom Score & IPSS Quality of Life Questions)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0, 02=SV2.0, 12=Week 12, 24=Week 24, 36=Week 36, 48=Week 48, 60=Week 60, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number that best describes your condition.*

	not at all	*less than 1 time in 5*	*less than half the time*	*about half the time*	*more than half the time*	*almost always*
7. Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
8. Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5
9. Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
10. Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5
11. Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5
12. Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5
	None	*1 time*	*2 times*	*3 times*	*4 times*	*5 or more times*
13. Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	0	1	2	3	4	5

14. *To be completed by the study coordinator:* *AUASS =* ☐☐☐☐ *(Total of items 7-13.)*

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October 9, 2008 CAM75 RS

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

Draft

CAMUS Clinical Trial
International Prostate Symptom Score (IPSS) For (CAM75)
(AUA Symptom Score & IPSS Quality of Life Questions)

Participant ID
2. [ ][ ][ ]S[ ][ ][ ]

Page Number
3. 2

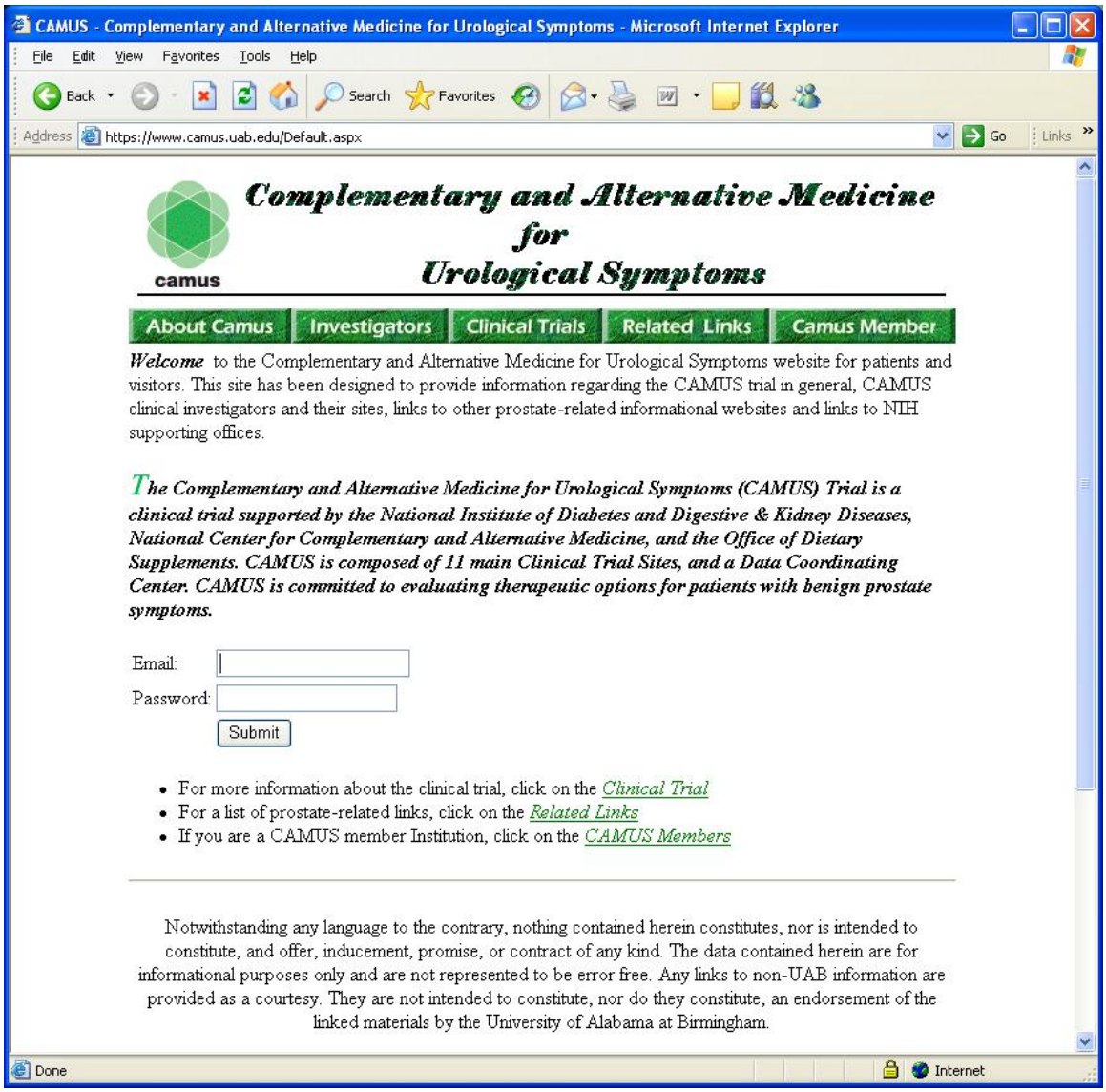
Visit Number
4. [ ][ ]

01=SV1.0 02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

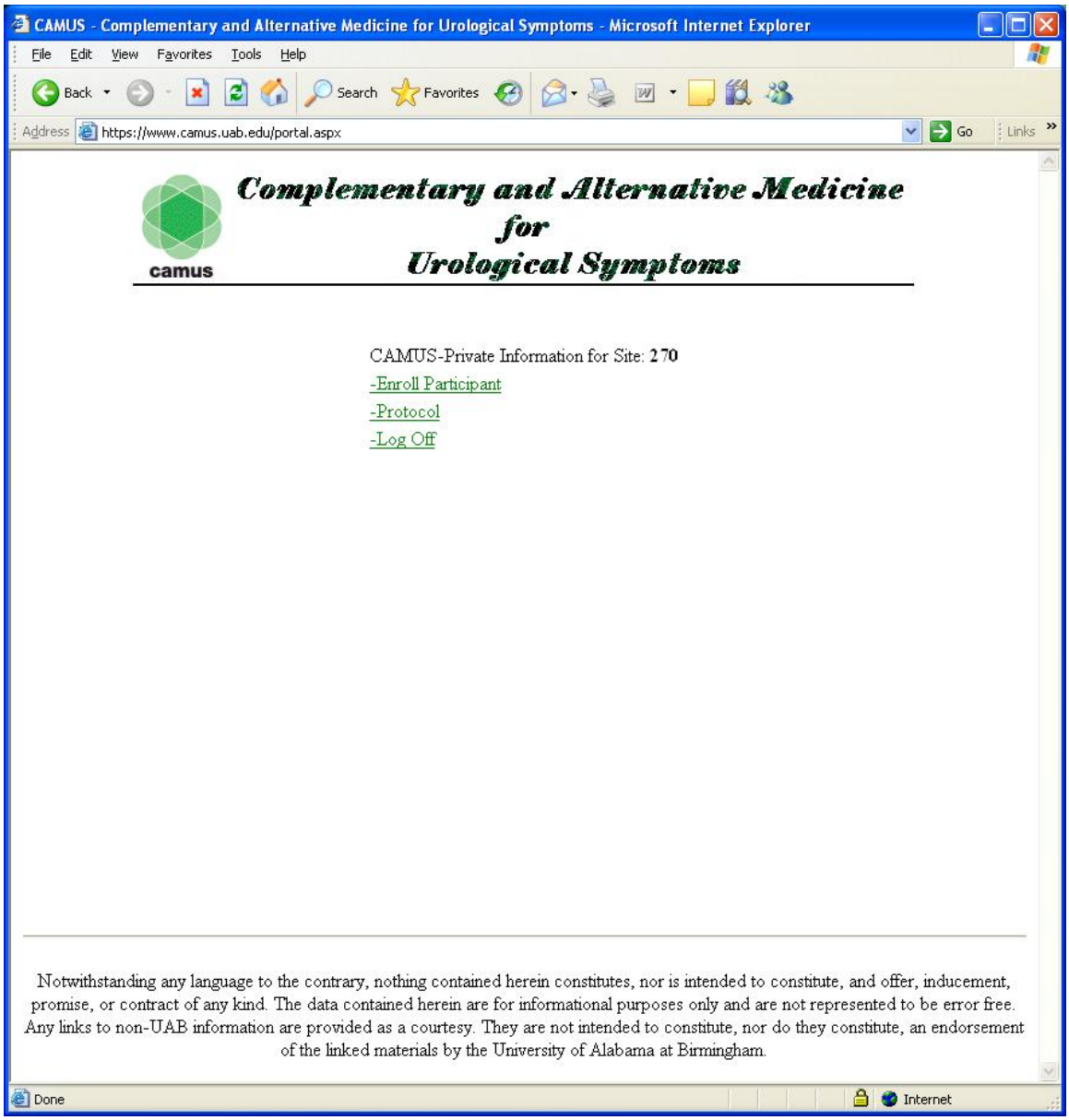
	Delighted	*Pleased*	*Mostly satisfied*	*Mixed-about equally satisfied and dissatisfied*	*Mostly dissatisfied*	*Unhappy*	*Terrible*
15. If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	1	2	3	4	5	6	7

	Not at all	*Less than 1 time in 5*	*Less than half the time*	*About half the time*	*More than half the time*	*Almost always*
16. Over the past month, how often when you felt the urge to urinate, did you leak urine before you could get to the toilet?	1	2	3	4	5	6

Once a participant is determined to be eligible for the study, a medical kit number can be obtained by visiting the CAMUS website https://www.camus.uab.edu. The following screen shot displays the home page.



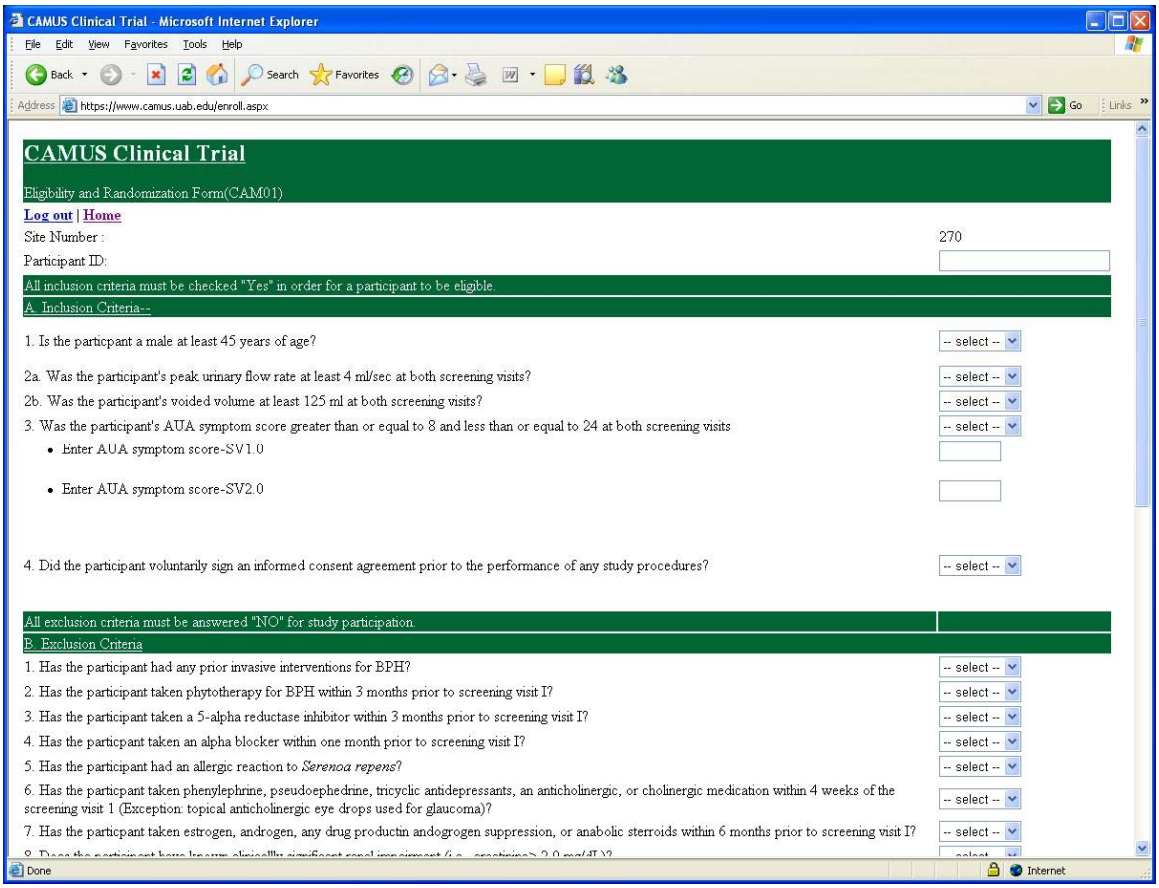
Once you enter the website, you will be prompted to click on one of three options.



To enroll a participant, click on 'Enroll Participant'. The screen shot below displays the Eligibility and Randomization Form (CAM01). The screens will guide you through the eligibility criteria. If any of the criteria are violated the system will not let you enroll the patient.

It is important to correctly enter the Participant ID number which begins with 101. If you enter 001, the enrollment cannot proceed. Also, if there is no activity detected for a while you could be logged out of the system. In this case, please log on again and re-start the enrollment process.

If you have any technical issues, please call the help desk at 205-934-7662.



Forms required for the baseline visit:

Form Number	Procedure	Completed By
CAM01	Eligibility and Randomization	Study Coordinator
CAM45	Hematology and EKG	Study Coordinator
CAM23/24	Assessment of Medicine	Study Coordinator
CAM 61	BPH Outcome Events	Study Coordinator
CAM 71	Jenkins Sleep Dysfunction Scale	Participant
CAM 72	Erectile Function	Participant
CAM 73	Ejaculatory Function	Participant
CAM 76	BPH Impact Index	Participant
CAM 78	NIH-Chronic Prostatitis Symptom Index	Participant

CAM01 – Eligibility and Randomization Form (REVISED 10/13/08)

This is the paper version of what you will see when you are ready to randomize the patient via the web-based enrollment system.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date for which you are completing the form (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Paste the Medication Kit # label.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-10: These fields contain the inclusion criteria. The answers to all inclusion criteria must be circled 'Yes' in order for a patient to be eligible for randomization.

Fields 11-34: These fields contain the exclusion criteria. The answers to all exclusion criteria must be circled 'No' in order for a participant to be eligible for randomization.

Fields 35-36: These fields are provided by the DCC.

Draft

CAMUS Clinical Trial
Eligibility and Randomization Form (CAM01)

1. Completed on ___/___/_____ (mm/dd/yyyy)

2. Participant ID ___S___

3. Page Number 1

4. Medication Label

5. Site# ___

6. Staff ID ___

Circle the appropriate number below

Instructions: Complete this form during both screening visits. Enter eligibility data in the CAMUS Web Data Entry System to receive a random treatment group assignment (in section C) for eligible participants.

A. Eligibility Inclusion Criteria ***(All inclusion criteria must be circled "Yes" in order for a participant to be eligible.)***

	Yes	No
7. Is the participant a male at least 45 years of age?	1	2
8a. Was the participant's peak urinary flow rate at least 4 ml/sec at both screening visits?	1	2
8b. Was the participant's voided volume at least 125 ml at both screening visits?	1	2
9. Was the participant's AUA symptom score greater than or equal to 8 and less than or equal to 24 at both screening visits?	1	2
10. Did the participant voluntarily sign an informed consent agreement prior to the performance of any study procedures?	1	2

B. Eligibility Exclusion Criteria ***(All exclusion criteria must be circled "No" in order for a participant to be eligible.)***

	Yes	No
11. Has the participant had any prior invasive interventions for BPH?	1	2
12. Has the participant taken phytotherapy for BPH within 3 months prior to screening visit 1?	1	2
13. Has the participant taken a 5-alpha reductase inhibitor within 3 months prior to screening visit 1?	1	2
14. Has the participant taken an alpha blocker within one month prior to screening visit 1?	1	2
15. Has the participant had an allergic reaction to *Serenoa repens*?	1	2

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CAMUS Clinical Trial
Eligibility and Randomization Form (CAM01)

Participant ID
2. [ ][ ][ ]S[ ][ ][ ]

Page Number
3. 2

	Yes	No
16. Has the participant taken phenylephrine, pseudoephedrine, tricyclic antidepressants, an anticholinergic, or cholinergic medication within 4 weeks of the screening visit 1 (Exception: topical anticholinergic eye drops used for glaucoma)?	1	2
17. Has the participant taken estrogen, androgen, any drug producing androgen suppression, or anabolic steroids within 6 months prior to screening visit 1?	1	2
18. Does the participant have known clinically significant renal impairment (i.e., creatinine > 2.0 mg/dL)?	1	2
19. Does the participant have an ALT(SGPT), AST(SGOT) or GGT value greater than 3 times the upper limit of normal, confirmed on a second measurement?	1	2
20. Does the participant have a prothrombin time greater than 3 seconds above the upper limit of normal or more than 3 seconds above the control value?	1	2
21. Does the participant have an electrocardiogram reading that suggests active ischemia?	1	2
22. Is the participant's PSA level greater than 10 ng/ml at screening?	1	2
23. Does the participant require daily use of a pad or device for incontinence, or have an ICSmaleIS score >14 at baseline?	1	2
24. Has the participant had an unstable medical condition within the past 3 months?	1	2
25. Does the participant have a history of or current evidence of carcinoma of the prostate or bladder, pelvic radiation or surgery, urethral stricture or prior surgery for bladder neck obstruction?	1	2
26. Does the participant have active urinary tract disease or has the participant undergone cystoscopy or biopsy of the prostate within 1 month prior to screening visit 1 or does he have an imminent need for urologic surgery?	1	2

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CAMUS Clinical Trial
Eligibility and Randomization Form (CAM01)

Participant ID
2. [ ][ ][ ]S[ ][ ][ ]

Page Number
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	Yes	No
27. Does the participant have known primary neurologic conditions such as multiple sclerosis or Parkinson's disease or other neurological diseases known to affect bladder function?	1	2
28. Has the participant had documented bacterial prostatitis within the past year?	1	2
29. Has the participant had two documented independent urinary tract infections of any type in the past year?	1	2
30. Does the participant have a known severe bleeding disorder or need for ongoing therapeutic anticoagulation with coumadin or heparin?	1	2
31. Does the participant have cancer which is not considered cured (except basal cell or squamous cell carcinoma of the skin)? A potential participant is considered cured if there has been no evidence of cancer within 5 years of study entry. A history of bladder cancer or prostate cancer is exclusionary whether the participant is considered cured or not?	1	2
32. Is the participant unable to follow protocol directions due to organic brain or psychiatric disease?	1	2
33. Does the participant have a history of alcoholism or any other substance abuse, which, in the opinion of the investigator, would affect compliance with the protocol?	1	2
34. Does the participant have any serious medical condition likely to impede successful completion of the long-term study?	1	2

C. Randomization ***(provided by DCC)***

35. Date randomized: [ ][ ]/[ ][ ]/[ ][ ][ ][ ]
mm dd yyyy

36. Med Kit #: M[ ][ ][ ][ ][ ]

CAM 45 – CBC, Serum Chemistries, Prothrombin Time and EKG Form (REVISED 10/14/08)

The old forms only ask if the values were normal or abnormal.
The old forms have boxes that you place a mark in.

The new forms record actual values for all the laboratory measures.
The new forms have the codes (1, = yes, 2 = no, 3 = don't know) that should be circled.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a complete blood count was obtained. If yes, complete a-e.

Field 8: Record the prothrombin time.

Field 9: Indicate whether or not a serum chemistry panel was obtained. If yes, complete a-i.

Field 10: For baseline, 24, 48 and 72 week visits, indicate whether or not an EKG was performed.

Recording whether an EKG is normal or abnormal with respect to recent MI or active Ischemia should be based on a Final report from a cardiologist.

All attempts should be made to ensure that these reports are received in a timely manner, so that the second screening visit and randomization visits can be scheduled in a timely fashion.

If any values are abnormal, complete the adverse events form (CAM81).

Draft

CAMUS Clinical Trial
CBC, Serum Chemistries, Prothrombin Time and EKG Form (CAM45)

1. Visit Date: ___ / ___ / ____ (mm / dd / yyyy)
2. Participant ID: ___S___
3. Page Number: 1
4. Visit Number: 01=SV1.0; 12=Week 12, 24=Week 24; 36=Week 36, 48=Week 48; 60=Week 60, 72=Week 72
5. Site#
6. Staff ID

Circle the appropriate number

7. Complete blood count:

	Yes	No
Was a complete blood count done at this visit?	1	2

If "No", skip to question 8. If "Yes", record below.

		Normal	Abnormal	Not Done
(a) Leukocyte count (WBC):	thou/cmm	1	2	3
(b) Erythrocyte count (RBC):	mill/cmm	1	2	3
(c) Hemoglobin:	g/dl	1	2	3
(d) Hematocrit:	%	1	2	3
(e) Platelet count:	thou/cmm	1	2	3

If any values are abnormal, complete adverse events form (CAM81).

8. Prothrombin time:

___.___ Seconds ___.___ Upper limit of normal or control value (Seconds) INR: ___.___

9. Serum chemistries:

	Yes	No
Was a serum chemistry panel done at this visit?	1	2

If "No", stop. If "Yes", record below.

		Normal	Abnormal	Not Done
(a) Sodium:	meq/l	1	2	3
(b) Potassium:	meq/l	1	2	3
(c) Chloride:	meq/l	1	2	3
(d) Bicarbonate:	meq/l	1	2	3
(e) Glucose:	meq/l	1	2	3
(f) Creatinine	meq/l	1	2	3
(g) ALT (SGPT):	IU/L	1	2	3
(h) AST (SGOT):	IU/L	1	2	3
(i) GGT:	IU/L	1	2	3

8. Complete this section every Baseline, 24, 48 and 72 week visit only.

Electrocardiogram:	1	2	3

If any values are abnormal, complete adverse events form (CAM81).

CAM23 – Concomitant Medication Form (REVISED 10/13/08)

Two separate medications can be reported on one form. For additional medications, please use an additional CAM23 and enter the page number in field 3.

Since the number of pages required for these forms will vary with the patient, page numbers have been omitted from these headers. Please be sure to fill in the page number along with other header information.

Do not duplicate medications listed on the Urology Medication Tracking Form (CAM 24).

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: If SV1, indicate whether or not the participant has taken any medications during the last 6 months. If this is not SV1, indicate whether or not the participant has started or stopped any urology medications since the last visit. **If yes, complete fields 8-23.**

Field 8: Enter the generic name of the medication.

Field 9: Enter the total dosage.

Field 10: Enter the dosage units. Refer to the dosage unit codes at the bottom of the form.

Field 11: Enter the frequency of dose. Refer to the frequency codes at the bottom of the form.

Field 12: Enter the mode of administration. Refer to the mode of administration codes at the bottom of the form.

Field 13: Enter the date the medication was started.

Field 14: Enter the date the medication was stopped **OR** check “Ongoing”.

Field 15: Indicate the primary reason for use or change.

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CAMUS Clinical Trial
Concomitant Medication Form (CAM23)

1. Visit Date ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)

2. Participant ID ☐☐☐S☐☐☐

3. Page Number ☐

4. Visit Number ☐☐

01=SV1.0	04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

5. Site# ☐☐☐

6. Staff ID ☐☐

Do not duplicate medications listed on the Urology Medication Tracking Form (CAM24). Number page(s) in upper right corner of the form.

Circle the appropriate number

	Yes	No	Don't Know
	1	2	3

7. If this is screening visit 1, has the participant taken any medications during the last 6 months? If this is not screening visit 1, since the last visit, has the participant started or stopped any medications ?

⇨ **If "Yes", continue to complete below.**

⇨ **If "No", stop here.**

8. **Medication** *(Give generic name):* _____

9. **Total Dosage:** _____ 10. **Dosage Units** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

11. **Frequency** ☐ *(See Codes below)* ⇨ If "other", Specify: _____ 12. **Mode of Administration** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

13. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨ 14. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

15. **Primary Reason for Use or Change:** _____

16. **Medication** *(Give generic name):* _____

17. **Total Dosage:** _____ 18. **Dosage Units** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

19. **Frequency** ☐ *(See Codes below)* ⇨ If "other", Specify: _____ 20. **Mode of Administration** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

21. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨ 22. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

23. **Primary Reason for Use or Change:** _____

Dosage Units Codes: **(1)** mg, **(2)** mcg or ug, **(3)** ml or cc, **(4)** units, **(5)** g, **(6)** Other (specify)

Frequency Codes: **(1)** Single Dose, **(2)** BID, **(3)** TID, **(4)** QID, **(5)** PRN, **(6)** Q4h, **(7)** Other (specify)

Mode of Administration Codes: **(1)** Intravenous, **(2)** Oral, (3) Intra-muscular, **(4)** Sub-lingual, **(5)** Intra-urethral, **(6)** Patches, **(7)** Other (specify)

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CAM24 – Urology Medication Tracking Form (REVISED 10/13/08)

Two separate medications can be reported on one form. For additional medications, please use an additional CAM24 and enter the page number in field 3.

Since the number of pages required for these forms will vary with the patient, page numbers have been omitted from these headers. Please be sure to fill in the page number along with other header information.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: If SV1, indicate whether or not the participant has taken any urology medications during the last 6 months. If this is not SV1, indicate whether or not the participant has started or stopped any urology medications since the last visit. **If yes, complete fields 8-21.**

Field 8: Enter the generic name of the medication.

Field 9: Enter the total dosage.

Field 10: Enter the dosage units. Refer to the dosage unit codes at the bottom of the form.

Field 11: Enter the frequency of dose. Refer to the frequency codes at the bottom of the form.

Field 12: Enter the mode of administration. Refer to the mode of administration codes at the bottom of the form.

Field 13: Enter the date the medication was started.

Field 14: Enter the date the medication was stopped **OR** check “Ongoing”.

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CAMUS Clinical Trial
Urology Medication Tracking Form (CAM24)

1. Visit Date: ___/___/____ (mm/dd/yyyy)
2. Participant ID: ____S____
3. Page Number: ____
4. Visit Number: ____ (01=SV1.0; 04=Week 4, 12=Week 12, 24=Week 24; 28=Week 28, 36=Week 36, 48=Week 48; 52=Week 52, 60=Week 60, 72=Week 72)
5. Site#: ____
6. Staff ID: ____

Do not duplicate medications listed on the Concomitant Medication Form (CAM23). Number page(s) in upper right corner of the form.

Circle the appropriate number

	Yes	No	Don't Know
7. If this is screening visit 1, has the participant taken any urology medications during the last 6 months? If this is not screening visit 1, since the last visit, has the participant started or stopped any urology medications?	1	2	3

⇨ **If "Yes", continue to complete below.**

⇨ **If "No", stop here.**

8. **Medication** *(Give generic name):* _____

9. **Total Dosage:** _____

10. **Dosage Units** ☐ ⇨ If "other", Specify: _____ *(See Codes below)*

11. **Frequency** *(See Codes below)* ☐ ⇨ If "other", Specify: _____

12. **Mode of Administration** *(See Codes below)* ☐ ⇨ If "other", Specify: _____

13. **Date Started** *(mm/dd/yyyy)* ___/___/____ **Ongoing:** ☐ *Or* ⇨ 14. **Date Stopped** *(mm/dd/yyyy)* ___/___/____

15. **Medication** *(Give generic name):* _____

16. **Total Dosage:** _____

17. **Dosage Units** ☐ ⇨ If "other", Specify: _____ *(See Codes below)*

18. **Frequency** *(See Codes below)* ☐ ⇨ If "other", Specify: _____

19. **Mode of Administration** *(See Codes below)* ☐ ⇨ If "other", Specify: _____

20. **Date Started** *(mm/dd/yyyy)* ___/___/____ **Ongoing:** ☐ *Or* ⇨ 21. **Date Stopped** *(mm/dd/yyyy)* ___/___/____

Dosage Units Codes: **(1)** mg, **(2)** mcg or ug, **(3)** ml or cc, **(4)** units, **(5)** g, **(6)** Other (specify)

Frequency Codes: **(1)** Single Dose, **(2)** BID, **(3)** TID, **(4)** QID, **(5)** PRN, **(6)** Q4h, **(7)** Other (specify)

Mode of Administration Codes: **(1)** Intravenous, **(2)** Oral, (3) Intra-muscular, **(4)** Sub-lingual, **(5)** Intra-urethral, **(6)** Patches, **(7)** Other (specify)

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CAM 61 – BPH Outcome Events Form (REVISED 10/13/08)

This form is completed each time a participant meets the protocol definition for BPH progression.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7a: Specify the classification of the BPH outcome.
If the classification is either 1, 2, or 3 complete Field 8.
If the classification is 4 complete Field 9.

Field 8a: Specify the type(s) of urinary event(s).

Field 9a: Specify the invasive or medical therapy for BPH or phytotherapy.

Field 9b: Specify the primary reason given by the participant for switching to another therapy for BPH.

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CAMUS Clinical Trial
BPH Outcome Events Form (CAM61)

1. Visit Date: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)

2. Participant ID: ☐☐☐S☐☐☐

3. Page Number: 1

4. Visit Number: ☐☐

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

5. Site#: ☐☐☐

6. Staff ID: ☐☐

To be completed each time a participant meets the protocol definition for BPH progression.

7. BPH Outcomes:

a. Specify the classification of the outcome for the participant below, check only one.

1. ☐ Acute urinary retention (Complete #8)
2. ☐ Recurrent symptomatic urinary tract infection or urosepsis (Complete #8)
3. ☐ New incontinence or progression of minor incontinence (Complete #8)
4. ☐ Crossover to invasive or medical therapy for BPH (Complete #9)

8. Urinary Event Specification:

a. Specify the type of urinary event (check all that apply):

	Date of last event (mm / dd / yyyy)
1. ☐ Acute urinary retention	☐☐/ ☐☐/ ☐☐☐☐
2. ☐ Recurrent symptomatic urinary tract infection or urosepsis	☐☐/ ☐☐/ ☐☐☐☐
3. ☐ New incontinence or progression of minor incontinence	☐☐/ ☐☐/ ☐☐☐☐

Investigator Signature Required on page 2.

Draft

CAMUS Clinical Trial
BPH Outcome Events Form (CAM61)

Participant ID
2. [ ][ ][ ]S[ ][ ][ ]

Page Number
3. 2

Visit Number
4. [ ][ ]

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

9. Crossover to Invasive or Medical Therapy for BPH or Phytotherapy Specification :

a. Specify the invasive or medical therapy for BPH or phytotherapy (check all that apply):

- ☐ TURP
- ☐ TUIP
- ☐ Radical prostatectomy
- ☐ Open prostatectomy
- ☐ TUNA
- ☐ Microwave therapy
- ☐ Laser therapy
- ☐ Stent

☐ Other invasive therapy
Specify other invasive therapy:
_____
_____

☐ Other phytotherapy
Specify other phytotherapy therapy:
_____
_____

☐ Other medical therapy
Specify other medical therapy:
_____
_____

b. Primary reason given by participant for switching to another therapy for BPH (check one):

1. ☐ Lack of improvement in prostate symptoms
2. ☐ Worsening of prostate symptoms
3. ☐ Intolerable side effects ⇨ Specify: _____
4. ☐ Other ⇨Specify: _____

Investigator Signature: _____ **Date:** _____

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CAM71 – Jenkins Sleep Dysfunction Scale Form (REVISED 10/10/08)
The CAM71S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6.

The participant completes fields 7-10.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-10: The participant completes these fields.

Draft

CAMUS Clinical Trial
Jenkins Sleep Dysfunction Scale Form (CAM71)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (03=Baseline; 24=Week 24, 48=Week 48, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number that best describes your condition.*

In the past month, how often did you:

	not at all	*1-3 days*	*4-7 days*	*8-14 days*	*15-21 days*	*22-31 days*
7. Have trouble falling asleep?	0	1	2	3	4	5
8. Wake up several times per night?	0	1	2	3	4	5
9. Have trouble staying asleep (including waking far too early)?	0	1	2	3	4	5
10. Wake up after your usual amount of sleep feeling tired and worn out?	0	1	2	3	4	5

CAM72 – Erectile Function Form (REVISED 10/09/08)
The CAM72S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6.

The participant completes fields 7-15

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-15: The participant completes these fields.

[redacted] Draft

CAMUS Clinical Trial
Erectile Function Form (CAM72)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)

2. Participant ID: ☐☐☐S☐☐☐

3. Page Number: 1

4. Visit Number: ☐☐ (03=Baseline; 24=Week 24, 48=Week 48, 72=Week 72)

5. Site#: ☐☐☐

6. Staff ID: ☐☐

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number that best describes your condition.*

	No Sexual Activity	Never or almost never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Always or almost always
In the past month:						
7. How often were you able to get an erection during sexual activity?	1	2	3	4	5	6
8. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	1	2	3	4	5	6
9. When you attempted sexual intercourse, how often were you able to penetrate your partner?	1	2	3	4	5	6
10. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?	1	2	3	4	5	6
11. When you had sexual stimulation or intercourse, how often did you ejaculate?	1	2	3	4	5	6
12. When you had sexual stimulation or intercourse, how often did you have the feeling of orgasm or climax?	1	2	3	4	5	6

Draft

CAMUS Clinical Trial
Erectile Function Form (CAM72)

Participant ID
2. | | | | S | | | |

Page Number
3. 2

Visit Number
4. | |

03=Baseline	24=Week 24 48=Week 48 72=Week 72

	Did not attempt intercourse	Extremely difficult	Very difficult	Difficult	Slightly difficult	Not difficult
13. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	1	2	3	4	5	6

	Very low	Low	Moderate	High	Very high
14. How do you rate your confidence that you could get and keep an erection?	1	2	3	4	5

	Very dissatisfied	Moderately dissatisfied	About equally satisfied and dissatisfied	Moderately satisfied	Very satisfied
15. If you have to spend the rest of your life with your erectile condition just the way it is now, how would you feel about that?	1	2	3	4	5

CAM73 – Ejaculatory Function Form (REVISED 10/09/08)
The CAM73S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6.

The participant completes fields 7-10

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-10: The participant completes these fields.

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CAMUS Clinical Trial
Ejaculatory Function Form (CAM73)

1. Visit Date: ___/___/____ (mm/dd/yyyy)
2. Participant ID: ___S___
3. Page Number: 1
4. Visit Number: 03=Baseline; 24=Week 24, 48=Week 48, 72=Week 72
5. Site#
6. Staff ID

This form is completed by the participant.

Instructions: *These questions are about male ejaculation. Ejaculation or cumming is the release of semen or cum during sexual climax. In answering these questions, we want to know about all of your ejaculations when having sexual activity. These could include ejaculations you have had with your wife or main partner, as well as with other partners, or ejaculations you could have had when masturbating by yourself. For each question, circle the appropriate number that best describes your condition.*

	All of the time	Most of the time	Some of the time	A little of the time	None of the time	No sexual activity
7. In the past month, how often have you been able to ejaculate when having sexual activity?	1	2	3	4	5	6

	As strong as it always was	A little less than it used to be	Somewhat less than it used to be	Much less than it used to be	Very much less than it used to be	Did not ejaculate
8. In the past month, how would you rate the strength or force of your ejaculation? Would you say it is...	1	2	3	4	5	6
9. In the past month, how would you rate the amount or volume of semen when you ejaculate? Would you say it is...	1	2	3	4	5	6

	Not at all bothered	A little bit bothered	Moderately bothered	Very bothered	Extremely bothered
10. In the past month, if you have had any ejaculation difficulties or have been unable to ejaculate, have you been bothered by this?	1	2	3	4	5

CAM76 – BPH Impact Index Form (REVISED 10/09/08)
The CAM76S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6 AND field 11.

The participant completes fields 7-10 and field 12.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-10: The participant completes these fields.

Field 11: The study coordinator calculates the BPH Impact Index Score.

Field 12: The participant completes this field.

[redacted] Draft

CAMUS Clinical Trial
BPH Impact Index Form (CAM76)

1. Visit Date: mm / dd / yyyy

2. Participant ID: [ ][ ][ ]S[ ][ ][ ]

3. Page Number: 1

4. Visit Number: [ ][ ] (02=SV2.0; 12=Week 12, 24=Week 24; 36=Week 36, 48=Week 48; 60=Week 60, 72=Week 72)

5. Site#: [ ][ ][ ]

6. Staff ID: [ ][ ]

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number that best describes your urinary condition.*

	None	*Only a little*	*Some*	*A lot*
7. Over the past month, how much physical discomfort did any urinary problems cause you?	0	1	2	3
8. Over the past month, how much did you worry about your health because of any urinary problems?	0	1	2	3

	Not at all bothersome	*Bothers me a little*	*Bothers me some*	*Bothers me a lot*
9. Overall, how bothersome has any trouble with urination been during the past month?	0	1	2	3

	None of the time	*A little of the time*	*Some of the time*	*Most of the time*	*All of the time*
10. Over the past month, how much of the time has any urinary problem kept you from doing the kinds of things you would usually do?	0	1	2	3	4

11. *To be completed by the study coordinator:* *BPH Impact Index Score =* [ ][ ][ ][ ]
(Total of items 7-10.)

	Worse	*No Change*	*A little better*	*A lot better*
12. Compared to the beginning of the study, how do you feel about your urination now?	1	2	3	4

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October 9, 2008 CAM76 RS

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

CAM78 – NIH-Chronic Prostatitis Symptom Index (NIH-CPSI) (REVISED 10/10/08)

The CAM78S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6 AND fields 16-18.

The participant completes fields 7-15.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-15: The participant completes these fields.

Fields 16-18: The study coordinator scores the NIH-Chronic Prostatitis Symptom Index Domains.

Draft

CAMUS Clinical Trial
NIH-Chronic Prostatitis Symptom Index (NIH-CPSI) (CAM78)

1. Visit Date: ___ / ___ / ____ (mm / dd / yyyy)
2. Participant ID: ___ S ___
3. Page Number: 1
4. Visit Number: ___ (03=Baseline; 24=Week 24, 48=Week 48, 72=Week 72)
5. Site#: ___
6. Staff ID: ___

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number.*

Pain or Discomfort

	Yes	No
7. In the past week, have you experienced any pain or discomfort in the following areas?		
(a) Area between rectum and testicles (perineum)?	1	0
(b) Testicles?	1	0
(c) Tip of the penis (not related to urination)?	1	0
(d) Below your waist in your pubic or bladder area?	1	0
8. In the past week, have you experienced:		
(a) Pain or burning during urination?	1	0
(b) Pain or discomfort during or after sexual climax (ejaculation)?	1	0

	Never	*Rarely*	*Sometimes*	*Often*	*Usually*	*Always*
9. How often have you had pain or discomfort in any of these areas over the last week?	0	1	2	3	4	5

10. Which number best describes your AVERAGE pain or discomfort on the days that you had it, over the last week?

0 1 2 3 4 5 6 7 8 9 10

NO PAIN — **PAIN AS BAD AS YOU CAN IMAGINE**

Urination

	not at all	*less than 1 time in 5*	*less than half the time*	*about half the time*	*more than half the time*	*almost always*
11. How often have you had a sensation of not emptying your bladder completely after you finished urinating, over the last week?	0	1	2	3	4	5

Draft

CAMUS Clinical Trial
NIH-Chronic Prostatitis Symptom Index (NIH-CPSI) (CAM78)

Participant ID
2. [ ][ ][ ]S[ ][ ][ ]

Page Number
3. 2

Visit Number
4. [ ][ ]

03=Baseline	24=Week 24 48=Week 48 72=Week 72

Urination Continued

	not at all	*less than 1 time in 5*	*less than half the time*	*about half the time*	*more than half the time*	*almost always*
12. How often have you had to urinate again less than two hours after you finished urinating, over the last week?	0	1	2	3	4	5

Impact of Symptoms

	None	*Only a little*	*Some*	*A lot*
13. How much have your symptoms kept you from doing the kinds of things you would usually do, over the last week?	0	1	2	3
14. How much did you think about your symptoms, over the last week?	0	1	2	3

Quality of Life

	Delighted	*Pleased*	*Mostly satisfied*	*Mixed (about equally satisfied and dissatisfied)*	*Mostly dissatisfied*	*Unhappy*	*Terrible*
15. If you were to spend the rest of your life with your symptoms just the way they have been during the last week, how would you feel about that?	0	1	2	3	4	5	6

To be completed by the study coordinator:

Scoring the NIH-Chronic Prostatitis Symptom Index Domains

16. *Pain:* Total of items 7a, 7b, 7c, 7d, 8a, 8b, 9, and 10 = [ ][ ]

17. *Urinary Symptoms:* Total of items 11 and 12 = [ ][ ]

18. *Quality of Life Impact:* Total of items 13, 14 and 15 [ ][ ]

FORMS REQUIRED FOR WEEKS 4, 28 and 52

CAM Form	Procedure	Completed By
22	Medical Follow-Up	Study Coordinator
23/24	Assessment of Medicine	Study Coordinator
31	Vital Signs	Study Coordinator
81	Adverse Events	Study Coordinator

CAM22 – History Update Form (REVISED 10/10/08)

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number.

Field 6: Enter the initials of the staff person completing the form.

Fields 7-12: The study coordinator completes these fields and also completes additional forms as directed by the answers provided.

Draft

CAMUS Clinical Trial
History Update Form (CAM22)

1. Visit Date: ___ / ___ / ____ (mm / dd / yyyy)

2. Participant ID: ___ S ___

3. Page Number: 1

4. Visit Number

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

5. Site#

6. Staff ID

Circle the appropriate number	Yes	No	Don't Know
7. Have there been changes in or new concomitant medications since the last visit? ⇨ **If yes, update concomitant medication form (CAM23).**	1	2	3
8. Have there been changes in or new urology medications since the last visit? ⇨ **If yes, update urology medication tracking form (CAM24).**	1	2	3
9. Has the participant experienced any new adverse events since the last visit? ⇨ **If yes, update adverse events form (CAM81).**	1	2	3
10. Have previously reported adverse events resolved or worsened since the last visit ? ⇨ **If yes, update adverse events form (CAM81).**	1	2	3
11. Does participant currently have a suprapubic catheter, use CIC/ISC, or had a catheter removed since the last visit?	1	2	3
12. Has the participant reached a protocol defined BPH outcome? ⇨ **If yes, update BPH outcome events form (CAM61).**	1	2	3

CAM23 – Concomitant Medication Form (REVISED 10/13/08)

Two separate medications can be reported on one form. For additional medications, please use an additional CAM23 and enter the page number in field 3.

Since the number of pages required for these forms will vary with the patient, page numbers have been omitted from these headers. Please be sure to fill in the page number along with other header information.

Do not duplicate medications listed on the Urology Medication Tracking Form (CAM 24).

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: If SV1, indicate whether or not the participant has taken any medications during the last 6 months. If this is not SV1, indicate whether or not the participant has started or stopped any urology medications since the last visit. **If yes, complete fields 8-23.**

Field 8: Enter the generic name of the medication.

Field 9: Enter the total dosage.

Field 10: Enter the dosage units. Refer to the dosage unit codes at the bottom of the form.

Field 11: Enter the frequency of dose. Refer to the frequency codes at the bottom of the form.

Field 12: Enter the mode of administration. Refer to the mode of administration codes at the bottom of the form.

Field 13: Enter the date the medication was started.

Field 14: Enter the date the medication was stopped **OR** check “Ongoing”.

Field 15: Indicate the primary reason for use or change.

Draft

CAMUS Clinical Trial
Concomitant Medication Form (CAM23)

1. Visit Date ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)

2. Participant ID ☐☐☐S☐☐☐

3. Page Number ☐

4. Visit Number ☐☐

01=SV1.0	04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

5. Site# ☐☐☐

6. Staff ID ☐☐

Do not duplicate medications listed on the Urology Medication Tracking Form (CAM24). Number page(s) in upper right corner of the form.

Circle the appropriate number

	Yes	No	Don't Know
	1	2	3

7. If this is screening visit 1, has the participant taken any medications during the last 6 months? If this is not screening visit 1, since the last visit, has the participant started or stopped any medications ?
   ⇨ **If "Yes", continue to complete below.**
   ⇨ **If "No", stop here.**

8. **Medication** *(Give generic name):* _____

9. **Total Dosage:** _____

10. **Dosage Units** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

11. **Frequency** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

12. **Mode of Administration** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

13. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨

14. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

15. **Primary Reason for Use or Change:** _____

16. **Medication** *(Give generic name):* _____

17. **Total Dosage:** _____

18. **Dosage Units** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

19. **Frequency** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

20. **Mode of Administration** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

21. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨

22. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

23. **Primary Reason for Use or Change:** _____

Dosage Units Codes: **(1)** mg, **(2)** mcg or ug, **(3)** ml or cc, **(4)** units, **(5)** g, **(6)** Other (specify)

Frequency Codes: **(1)** Single Dose, **(2)** BID, **(3)** TID, **(4)** QID, **(5)** PRN, **(6)** Q4h, **(7)** Other (specify)

Mode of Administration Codes: **(1)** Intravenous, **(2)** Oral, (3) Intra-muscular, **(4)** Sub-lingual, **(5)** Intra-urethral, **(6)** Patches, **(7)** Other (specify)

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Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

CAM24 – Urology Medication Tracking Form (REVISED 10/13/08)

Two separate medications can be reported on one form. For additional medications, please use an additional CAM24 and enter the page number in field 3.

Since the number of pages required for these forms will vary with the patient, page numbers have been omitted from these headers. Please be sure to fill in the page number along with other header information.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: If SV1, indicate whether or not the participant has taken any urology medications during the last 6 months. If this is not SV1, indicate whether or not the participant has started or stopped any urology medications since the last visit. **If yes, complete fields 8-21.**

Field 8: Enter the generic name of the medication.

Field 9: Enter the total dosage.

Field 10: Enter the dosage units. Refer to the dosage unit codes at the bottom of the form.

Field 11: Enter the frequency of dose. Refer to the frequency codes at the bottom of the form.

Field 12: Enter the mode of administration. Refer to the mode of administration codes at the bottom of the form.

Field 13: Enter the date the medication was started.

Field 14: Enter the date the medication was stopped **OR** check “Ongoing”.

Draft

CAMUS Clinical Trial
Urology Medication Tracking Form (CAM24)

1. Visit Date: mm / dd / yyyy
2. Participant ID: S
3. Page Number
4. Visit Number: 01=SV1.0; 04=Week 4, 12=Week 12, 24=Week 24; 28=Week 28, 36=Week 36, 48=Week 48; 52=Week 52, 60=Week 60, 72=Week 72
5. Site#
6. Staff ID

Do not duplicate medications listed on the Concomitant Medication Form (CAM23). Number page(s) in upper right corner of the form.

Circle the appropriate number

	Yes	No	Don't Know
7. If this is screening visit 1, has the participant taken any urology medications during the last 6 months? If this is not screening visit 1, since the last visit, has the participant started or stopped any urology medications?	1	2	3

⇨ **If "Yes", continue to complete below.**

⇨ **If "No", stop here.**

8. **Medication** *(Give generic name):* _____

9. **Total Dosage:** _____

10. **Dosage Units** ☐ ⇨ If "other", Specify: _____ *(See Codes below)*

11. **Frequency** ☐ ⇨ If "other", Specify: _____ *(See Codes below)*

12. **Mode of Administration** ☐ ⇨ If "other", Specify: _____ *(See Codes below)*

13. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨ 14. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

15. **Medication** *(Give generic name):* _____

16. **Total Dosage:** _____

17. **Dosage Units** ☐ ⇨ If "other", Specify: _____ *(See Codes below)*

18. **Frequency** ☐ ⇨ If "other", Specify: _____ *(See Codes below)*

19. **Mode of Administration** ☐ ⇨ If "other", Specify: _____ *(See Codes below)*

20. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨ 21. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

Dosage Units Codes: **(1)** mg, **(2)** mcg or ug, **(3)** ml or cc, **(4)** units, **(5)** g, **(6)** Other (specify)

Frequency Codes: **(1)** Single Dose, **(2)** BID, **(3)** TID, **(4)** QID, **(5)** PRN, **(6)** Q4h, **(7)** Other (specify)

Mode of Administration Codes: **(1)** Intravenous, **(2)** Oral, (3) Intra-muscular, **(4)** Sub-lingual, **(5)** Intra-urethral, **(6)** Patches, **(7)** Other (specify)

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Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

CAM 31 – Vital Signs Form (REVISED 10/10/08)

The old forms for this study ask for the BP to be taken both lying down and standing.

For this study, you only need to take two consecutive measurements five minutes apart, both sitting down

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the 3-digit site number.

Field 4: This field is pre-filled.

Field 5: Enter the visit number. Refer to the table.

Field 6: Enter the initials of the staff person completing the form.

Field 7: Check the appropriate visit type.

The vital signs have to be recorded at the first screening visit or the second visit.

Field 8: Indicate whether or not vital signs were obtained. If yes, complete questions 9-11.

Draft

CAMUS Clinical Trial
Vital Signs Form (CAM31)

Visit Date
1. ☐☐/ ☐☐/ ☐☐☐☐
mm dd yyyy

2. Participant ID ☐☐☐S☐☐☐

3. Site# ☐☐☐

Page Number
4. 1

Visit Number
5. ☐☐

01=SV1.0 02=SV2.0	04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

Staff ID
6. ☐☐

Visit type
7. ☐ In-Clinic Visit
☐ Telephone Interview

Circle the appropriate number	Yes	No
8. Were vital signs done at this visit? ⇨ **If "No", stop here.** **If "Yes", record below.**	1	2

9. Height: ☐☐ inches (In-Clinic Only)

10. Weight: ☐☐☐ pounds (In-Clinic Only)

11. Seated measurements (reading 1 taken immediately, reading 2 taken 1 minute later):

(a) Blood pressure reading 1 ☐☐☐ / ☐☐☐ mm Hg
Systolic Diastolic

(b) Heart rate reading 1 ☐☐☐ bpm

(c) Time of Day 1 ☐☐☐☐ ☐ AM ☐ PM

(d) Blood pressure reading 2 ☐☐☐ / ☐☐☐ mm Hg
Systolic Diastolic

(e) Heart rate reading 2 ☐☐☐ bpm

CAM81 – Adverse Event Form (REVISED 10/13/08)

An adverse event is an unexpected medical problem that happens during treatment with a drug or other therapy. Adverse events do not have to be caused by the drug or therapy, and they may be mild, moderate, or severe. **All adverse events, regardless of severity, and whether or not ascribed to the study drug administration, should be recorded on CAM81.** All grade 3, 4 and 5 adverse events will be reviewed by the Clinical Review Committee.

Please refer to the document entitled 'SAE reporting Guidelines' provided by the American College of Surgeons – Oncology Group in the Appendix, for more details on the grading SAEs, attributing causes to SAEs and reporting of SAEs.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not the participant has experienced an adverse event since the last visit.

If yes, complete fields 8-18. (An additional event can be reported in fields 9-29.) Please refer to the table at the bottom of the page for applicable codes.

Draft

CAMUS Clinical Trial
Adverse Event Form (CAM81)

1. Visit Date ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)

2. Participant ID ☐☐☐S☐☐☐

3. Page Number ☐

4. Visit Number ☐☐

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

5. Site# ☐☐☐

6. Staff ID ☐☐

Circle the appropriate number

	Yes	No	
7. Has the participant experienced an adverse event since the last visit ?	1	2	⇨ If "Yes", record below. ⇨ If "No", stop here.

8. **MEDDRA Code:** ☐☐☐☐☐☐☐☐

9. **Description:** _____

10. **Date of Onset:** ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy) **Continuing** ☐ **OR** 11. **Date Resolved:** ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)

12. **Serious?** ☐ No ☐ Yes ⇨ *Complete SAE Form (CAM82)* **13. Severity** *(See Codes):* ☐

14. **Relationship to Study** *(See Codes):* ☐ **15. Outcome** *(See Codes):* ☐ **16. Anticipated?** ☐ No ☐ Yes

17. **Action Taken** 1 2 3 4 5 6 *(See Codes & circle all that apply):* **18. Action Taken Regarding Study Drug** *(See Codes):* ☐

19. **MEDDRA Code:** ☐☐☐☐☐☐☐☐

20. **Description:** _____

21. **Date of Onset:** ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy) **Continuing** ☐ **OR** 22. **Date Resolved:** ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)

23. **Serious?** ☐ No ☐ Yes ⇨ *Complete SAE Form (CAM82)* **24. Severity** *(See Codes):* ☐

25. **Relationship to Study** *(See Codes):* ☐ **26. Outcome** *(See Codes):* ☐ **27. Anticipated?** ☐ No ☐ Yes

28. **Action Taken** 1 2 3 4 5 6 *(See Codes & circle all that apply):* **29. Action Taken Regarding Study Drug** *(See Codes):* ☐

Relationship to Study Codes: (1) Unrelated, (2) Unlikely, (3) Possible, (4) Probable, (5) Definite

Severity: (1) Mild, (2) Moderate, (3) Severe, (4) Life Threatening, (5) Death

Outcome Codes: (1) Complete recovery w/o residual effect, (2) Recovered w/ residual effect, (3) Recovered w/ persistent effect, (4) Not yet recovered, (5) Died

Action Taken Codes: (1) Self or OTC treatment, (2) Office, clinic, ER, or out-pt visit, (3) In-pt visit or hosp admit, (4) Rx, (5) Procedure performed, (6) None

Action Taken Regarding Study Drug Codes: (0) Not applicable, (1) None, (2) Reduced, (3) Interrupted, (4) Discontinued

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October 13, 2008 CAM81 RS

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

FORMS REQUIRED FOR VISITS FOR WEEKS 12, 24, 36, 48 and 60

CAM Form	Procedure	Completed By
22	Medical Follow-Up	Study Coordinator
23/24	Assessment of Medicine	Study Coordinator
31	Vital Signs	Study Coordinator
41	PSA	Study Coordinator
42	Uroflow Measurement	Study Coordinator
45	Hematology and EKG	Study Coordinator
46	Urinalysis	Study Coordinator
47	Serum Banking	Study Coordinator
71	Jenkins Sleep Dysfunction Scale	Participant
74	Bladder Function	Participant
75	International Prostate Symptom Score (IPSS)	Participant
77	Subject Global Assessment	Participant
79	Participant Treatment Perception Form	Participant
81	Adverse Events	Study Coordinator

CAM22 – History Update Form (REVISED 10/10/08)

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number.

Field 6: Enter the initials of the staff person completing the form.

Fields 7-12: The study coordinator completes these fields and also completes additional forms as directed by the answers provided.

Draft

CAMUS Clinical Trial
History Update Form (CAM22)

1. Visit Date: ___ / ___ / ____ (mm / dd / yyyy)
2. Participant ID: ___S___
3. Page Number: 1
4. Visit Number: ___

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

5. Site#: ___
6. Staff ID: ___

Circle the appropriate number	Yes	No	Don't Know
7. Have there been changes in or new concomitant medications since the last visit? **⇨ If yes, update concomitant medication form (CAM23).**	1	2	3
8. Have there been changes in or new urology medications since the last visit? **⇨ If yes, update urology medication tracking form (CAM24).**	1	2	3
9. Has the participant experienced any new adverse events since the last visit? **⇨ If yes, update adverse events form (CAM81).**	1	2	3
10. Have previously reported adverse events resolved or worsened since the last visit ? **⇨ If yes, update adverse events form (CAM81).**	1	2	3
11. Does participant currently have a suprapubic catheter, use CIC/ISC, or had a catheter removed since the last visit?	1	2	3
12. Has the participant reached a protocol defined BPH outcome? **⇨ If yes, update BPH outcome events form (CAM61).**	1	2	3

CAM23 – Concomitant Medication Form (REVISED 10/13/08)

Two separate medications can be reported on one form. For additional medications, please use an additional CAM23 and enter the page number in field 3.

Since the number of pages required for these forms will vary with the patient, page numbers have been omitted from these headers. Please be sure to fill in the page number along with other header information.

Do not duplicate medications listed on the Urology Medication Tracking Form (CAM 24).

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: If SV1, indicate whether or not the participant has taken any medications during the last 6 months. If this is not SV1, indicate whether or not the participant has started or stopped any urology medications since the last visit. **If yes, complete fields 8-23.**

Field 8: Enter the generic name of the medication.

Field 9: Enter the total dosage.

Field 10: Enter the dosage units. Refer to the dosage unit codes at the bottom of the form.

Field 11: Enter the frequency of dose. Refer to the frequency codes at the bottom of the form.

Field 12: Enter the mode of administration. Refer to the mode of administration codes at the bottom of the form.

Field 13: Enter the date the medication was started.

Field 14: Enter the date the medication was stopped **OR** check “Ongoing”.

Field 15: Indicate the primary reason for use or change.

Draft

CAMUS Clinical Trial
Concomitant Medication Form (CAM23)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: ☐
4. Visit Number: ☐☐ (01=SV1.0; 04=Week 4, 12=Week 12, 24=Week 24; 28=Week 28, 36=Week 36, 48=Week 48; 52=Week 52, 60=Week 60, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

Do not duplicate medications listed on the Urology Medication Tracking Form (CAM24). Number page(s) in upper right corner of the form.

Circle the appropriate number

	Yes	No	Don't Know
	1	2	3

7. If this is screening visit 1, has the participant taken any medications during the last 6 months? If this is not screening visit 1, since the last visit, has the participant started or stopped any medications ?
   ⇨ **If "Yes", continue to complete below.**
   ⇨ **If "No", stop here.**

8. **Medication** *(Give generic name):* _____

9. **Total Dosage:** _____ 10. **Dosage Units** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

11. **Frequency** ☐ *(See Codes below)* ⇨ If "other", Specify: _____ 12. **Mode of Administration** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

13. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨ 14. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

15. **Primary Reason for Use or Change:** _____

16. **Medication** *(Give generic name):* _____

17. **Total Dosage:** _____ 18. **Dosage Units** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

19. **Frequency** ☐ *(See Codes below)* ⇨ If "other", Specify: _____ 20. **Mode of Administration** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

21. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨ 22. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

23. **Primary Reason for Use or Change:** _____

Dosage Units Codes: (1) mg, (2) mcg or ug, (3) ml or cc, (4) units, (5) g, (6) Other (specify)

Frequency Codes: (1) Single Dose, (2) BID, (3) TID, (4) QID, (5) PRN, (6) Q4h, (7) Other (specify)

Mode of Administration Codes: (1) Intravenous, (2) Oral, (3) Intra-muscular, (4) Sub-lingual, (5) Intra-urethral, (6) Patches, (7) Other (specify)

For Official use only

October 13, 2008 CAM23 RS

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

CAM24 – Urology Medication Tracking Form (REVISED 10/13/08)

Two separate medications can be reported on one form. For additional medications, please use an additional CAM24 and enter the page number in field 3.

Since the number of pages required for these forms will vary with the patient, page numbers have been omitted from these headers. Please be sure to fill in the page number along with other header information.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: If SV1, indicate whether or not the participant has taken any urology medications during the last 6 months. If this is not SV1, indicate whether or not the participant has started or stopped any urology medications since the last visit. **If yes, complete fields 8-21.**

Field 8: Enter the generic name of the medication.

Field 9: Enter the total dosage.

Field 10: Enter the dosage units. Refer to the dosage unit codes at the bottom of the form.

Field 11: Enter the frequency of dose. Refer to the frequency codes at the bottom of the form.

Field 12: Enter the mode of administration. Refer to the mode of administration codes at the bottom of the form.

Field 13: Enter the date the medication was started.

Field 14: Enter the date the medication was stopped **OR** check “Ongoing”.

Draft

CAMUS Clinical Trial
Urology Medication Tracking Form (CAM24)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: ☐
4. Visit Number: ☐☐

01=SV1.0	04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

5. Site#: ☐☐☐
6. Staff ID: ☐☐

Do not duplicate medications listed on the Concomitant Medication Form (CAM23). Number page(s) in upper right corner of the form.

Circle the appropriate number

	Yes	No	Don't Know
	1	2	3

7. If this is screening visit 1, has the participant taken any urology medications during the last 6 months? If this is not screening visit 1, since the last visit, has the participant started or stopped any urology medications?

⇨ **If "Yes", continue to complete below.**

⇨ **If "No", stop here.**

8. **Medication** *(Give generic name):* _____

9. **Total Dosage:** _____ 10. **Dosage Units** ☐ ⇨ If "other", Specify: _____
(See Codes below)

11. **Frequency** *(See Codes below)* ☐ ⇨ If "other", Specify: _____ 12. **Mode of Administration** *(See Codes below)* ☐ ⇨ If "other", Specify: _____

13. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨ 14. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

15. **Medication** *(Give generic name):* _____

16. **Total Dosage:** _____ 17. **Dosage Units** ☐ ⇨ If "other", Specify: _____
(See Codes below)

18. **Frequency** *(See Codes below)* ☐ ⇨ If "other", Specify: _____ 19. **Mode of Administration** *(See Codes below)* ☐ ⇨ If "other", Specify: _____

20. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨ 21. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

Dosage Units Codes: **(1)** mg, **(2)** mcg or ug, **(3)** ml or cc, **(4)** units, **(5)** g, **(6)** Other (specify)

Frequency Codes: **(1)** Single Dose, **(2)** BID, **(3)** TID, **(4)** QID, **(5)** PRN, **(6)** Q4h, **(7)** Other (specify)

Mode of Administration Codes: **(1)** Intravenous, **(2)** Oral, (3) Intra-muscular, **(4)** Sub-lingual, **(5)** Intra-urethral, **(6)** Patches, **(7)** Other (specify)

For Official use only

October 13, 2008 CAM24 RS

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

CAM 31 – Vital Signs Form (REVISED 10/10/08)

The old forms for this study ask for the BP to be taken both lying down and standing.

For this study, you only need to take two consecutive measurements five minutes apart, both sitting down

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the 3-digit site number.

Field 4: This field is pre-filled.

Field 5: Enter the visit number. Refer to the table.

Field 6: Enter the initials of the staff person completing the form.

Field 7: Check the appropriate visit type.

The vital signs have to be recorded at the first screening visit or the second visit.

Field 8: Indicate whether or not vital signs were obtained. If yes, complete questions 9-11.

Draft

CAMUS Clinical Trial
Vital Signs Form (CAM31)

1. Visit Date: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Site#: ☐☐☐
4. Page Number: 1
5. Visit Number: ☐☐ (01=SV1.0, 02=SV2.0, 04=Week 4, 12=Week 12, 24=Week 24, 28=Week 28, 36=Week 36, 48=Week 48, 52=Week 52, 60=Week 60, 72=Week 72)
6. Staff ID: ☐☐
7. Visit type: ☐ In-Clinic Visit ☐ Telephone Interview

Circle the appropriate number	Yes	No
8. Were vital signs done at this visit? ⇨ **If "No", stop here. If "Yes", record below.**	1	2

9. Height: ☐☐ inches (In-Clinic Only)

10. Weight: ☐☐☐ pounds (In-Clinic Only)

11. Seated measurements (reading 1 taken immediately, reading 2 taken 1 minute later):

(a) Blood pressure reading 1: ☐☐☐ (Systolic) / ☐☐☐ (Diastolic) mm Hg

(b) Heart rate reading 1: ☐☐☐ bpm

(c) Time of Day 1: ☐☐☐☐ ☐ AM ☐ PM

(d) Blood pressure reading 2: ☐☐☐ (Systolic) / ☐☐☐ (Diastolic) mm Hg

(e) Heart rate reading 2: ☐☐☐ bpm

CAM41 – PSA Sample Collection (REVISED 10/10/08)

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

A PSA level above 10ng/ml is an exclusionary criterion.

All PSA levels for the study are done at the same laboratory. The blood sample has to be collected and sent to the laboratory as set forth in the section on sample collection.

When the PSA level comes back, it is recorded on this same form.

In the old forms where there is only one decimal place, please just record the first number after the decimal. **There is no need to round up or down**.

Field 7: Indicate whether or not a serum PSA sample was collected. If yes, record the date of collection and complete fields 8-10.

Field 8: Indicate whether or not the serum PSA sample was shipped to central lab.

Field 9: Record the date of shipment.

Field 10: Record the PSA results.

[redacted] Draft

CAMUS Clinical Trial
PSA Sample Collection (CAM41)

1. Visit Date: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0; 24=Week 24, 48=Week 48, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

Circle the appropriate number

Serum PSA:	**Yes**	**No**
7. Was a serum PSA sample collected at this visit?	1	2
⇨ If "Yes", record date of collection. ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)		
⇨ If "No", STOP.		
8. *Was a serum PSA sample shipped to central lab?	1	2

9. *If "Yes", record the date of shipment: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)

10. PSA results from Central Lab: ☐☐.☐☐ ng/ml

For screening visit 1, excluded if serum prostate specific antigen level > 10 ng/ml.

**Does not apply to site# 277*

CAM42 – Uroflow Measurement Form (REVISED 10/10/08)

This form records information from the Uroflow tests.

Peak flow rate < 4 ml/sec and voided volume < 125 ml are both exclusionary criteria.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not uroflow measurements were obtained. If yes, complete fields 8-14.

[redacted] Draft

CAMUS Clinical Trial
Uroflow Measurement Form (CAM42)

Visit Date: [ ][ ]/ mm / [ ][ ]/ dd / [ ][ ][ ][ ] yyyy

2. Participant ID: [ ][ ][ ] S [ ][ ][ ]

Page Number 3. [1]

Visit Number: [ ][ ]

01=SV1.0 02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

5. Site# [ ][ ][ ]

6. Staff ID [ ][ ]

Circle the appropriate number	Yes	No
7. Were uroflow measurements done at this visit?	1	2

⇨ **If "No", stop here.**
If "Yes", record below.

8. Voiding time: [ ][ ][ ] sec

9. Flow time: [ ][ ][ ] sec

10. Time to maximum flow: [ ][ ][ ] sec

11. Peak flow rate: [ ][ ].[ ][ ] ml/sec

For screening visits 1 and 2: Excluded if peak flow rate is less than 4 ml/sec.

12. Mean flow rate: [ ][ ].[ ][ ] ml/sec

13. Voided volume: [ ][ ][ ][ ] ml

For screening visits: Excluded if voided volume < 125 ml.

14. Post-void residual: [ ][ ][ ] ml

CAM45 – CBC, Serum Chemistries, Prothrombin Time and EKG Form (REVISED 10/14/08)

The old forms only ask if the values were normal or abnormal.
The old forms have boxes that you place a mark in.

The new forms record actual values for all the laboratory measures.
The new forms have the codes (1, = yes, 2 = no, 3 = don't know) that should be circled.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a complete blood count was obtained. If yes, complete a-e.

Field 8: Record the prothrombin time.

Field 9: Indicate whether or not a serum chemistry panel was obtained. If yes, complete a-i.

Field 10: For baseline, 24, 48 and 72 week visits, indicate whether or not an EKG was performed.

Recording whether an EKG is normal or abnormal with respect to recent MI or active Ischemia should be based on a Final report from a cardiologist.

All attempts should be made to ensure that these reports are received in a timely manner, so that the second screening visit and randomization visits can be scheduled in a timely fashion.

If any values are abnormal, complete the adverse events form (CAM81).

Draft

CAMUS Clinical Trial
CBC, Serum Chemistries, Prothrombin Time and EKG Form (CAM45)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0; 12=Week 12, 24=Week 24; 36=Week 36, 48=Week 48; 60=Week 60, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

Circle the appropriate number

7. Complete blood count:

	Yes	No
Was a complete blood count done at this visit?	1	2

If "No", skip to question 8. If "Yes", record below.

		Normal	Abnormal	Not Done
(a) Leukocyte count (WBC):	☐☐.☐☐ thou/cmm	1	2	3
(b) Erythrocyte count (RBC):	☐☐.☐☐ mill/cmm	1	2	3
(c) Hemoglobin:	☐☐.☐☐ g/dl	1	2	3
(d) Hematocrit:	☐☐.☐☐ %	1	2	3
(e) Platelet count:	☐☐.☐☐ thou/cmm	1	2	3

If any values are abnormal, complete adverse events form (CAM81).

8. Prothrombin time:

☐☐.☐☐ **Seconds** ☐☐.☐☐ **Upper limit of normal or control value (Seconds)** **INR:** ☐.☐☐

9. Serum chemistries:

	Yes	No
Was a serum chemistry panel done at this visit?	1	2

If "No", stop. If "Yes", record below.

		Normal	Abnormal	Not Done
(a) Sodium:	☐☐☐.☐☐ meq/l	1	2	3
(b) Potassium:	☐☐☐.☐☐ meq/l	1	2	3
(c) Chloride:	☐☐☐.☐☐ meq/l	1	2	3
(d) Bicarbonate:	☐☐.☐☐ meq/l	1	2	3
(e) Glucose:	☐☐☐.☐☐ meq/l	1	2	3
(f) Creatinine	☐☐☐.☐☐ meq/l	1	2	3
(g) ALT (SGPT):	☐☐.☐☐ IU/L	1	2	3
(h) AST (SGOT):	☐☐.☐☐ IU/L	1	2	3
(i) GGT:	☐☐.☐☐ IU/L	1	2	3

8. Complete this section every Baseline, 24, 48 and 72 week visit only.

Electrocardiogram:	1	2	3

If any values are abnormal, complete adverse events form (CAM81).

CAM46 – Urinalysis Form (REVISED 10/10/08)

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a urinalysis was performed. If yes, complete fields 8-9

Field 8: Record the results based on the dipstick test.

Field 9: Record the results based on the microscopic urinalysis.

Draft

CAMUS Clinical Trial
Urinalysis Form (CAM46)

Page Number 3. 1

1. Visit Date ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

2. Participant ID ☐☐☐S☐☐☐

4. Visit Number ☐☐ (01=SV1.0, 72=Week 72)

5. Site# ☐☐☐

6. Staff ID ☐☐

Circle the appropriate number	Yes	No
7. Was an urinalysis done at this visit?	1	2

⇨ **If "Yes", record the results below.**

⇨ **If "No", stop.**

(8) Dipstick

(a) pH: ☐.☐

	0	*trace*	*1+*	*2+*	*3+*	*4+*
(b) Glucose	1	2	3	4	5	6
(c) Blood	1	2	3	4	5	6
(d) Ketones	1	2	3	4	5	6
(e) Protein	1	2	3	4	5	6
(f) Leukocyte esterase	1	2	3	4	5	6

(9) If dipstick is positive (> 0) for blood or leukocyte esterase, send specimen for microscopic urinalysis and code results below.

	none, negative, WNL	*1-5, trace, present, slight, rare*	*6-15, moderate*	*16-30, many, frequent*	*>30, innumerable, TNTC*
(a) WBC	1	2	3	4	5
(b) RBC	1	2	3	4	5
(c) Epithelial cells	1	2	3	4	5
(d) Mucous	1	2	3	4	5
(e) Bacteria	1	2	3	4	5
(f) Casts hyaline	1	2	3	4	5
(g) Casts other	1	2	3	4	5

For Official use only

October 10, 2008 CAM46 RS

[redacted]

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

CAM47 – Serum for Banking Form (REVISED 10/10/08)

If the patient has consented to it, a serum sample from the patient collected at the first visit and the separation visit is to be sent to the NIDDK repository. The samples are being collected and stored for future ancillary studies.

This form is used to identify patients whose sample is collected during SV1.0 and sent to the NIDDK.

If no sample is collected, the reasons for not collecting are also recorded.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a serum sample was collected.

Field 8: Enter the date of collection if applicable.

Field 9: Indicate the reason specimens were not obtained if applicable.

Field 10: Indicate whether or not the sample was shipped.

Field 11: Enter the date of shipment if applicable.

Draft

CAMUS Clinical Trial
Serum for Banking Form (CAM47)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

2. Participant ID: ☐☐☐S☐☐☐

3. Page Number: 1

4. Visit Number: ☐☐ (01=SV1.0, 72=Week 72)

5. Site#: ☐☐☐

6. Staff ID: ☐☐

Circle the appropriate number

	Yes	No
7. Was a serum sample collected at this visit?	1	2

8. If "Yes", Date of collection: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

9. If specimens were not obtained for CAMUS, please indicate reason (Check only one).

☐ (1)Patient refused to give informed consent for CAMUS serum studies (banking).

☐ (2)Patient was not asked to consider CAMUS serum studies (banking).

☐ (3)Other, specify: _____

	Yes	No
10. Was a serum sample shipped to NIDDK repository?	1	2

11. If "Yes", record the date of shipment: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

CAM71 – Jenkins Sleep Dysfunction Scale Form (REVISED 10/10/08)
The CAM71S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6.

The participant completes fields 7-10.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-10: The participant completes these fields.

Draft

CAMUS Clinical Trial
Jenkins Sleep Dysfunction Scale Form (CAM71)

1. Visit Date: ___/___/____ (mm/dd/yyyy)
2. Participant ID: ___S___
3. Page Number: 1
4. Visit Number: ___ (03=Baseline; 24=Week 24, 48=Week 48, 72=Week 72)
5. Site#: ___
6. Staff ID: ___

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number that best describes your condition.*

In the past month, how often did you:

	not at all	*1-3 days*	*4-7 days*	*8-14 days*	*15-21 days*	*22-31 days*
7. Have trouble falling asleep?	0	1	2	3	4	5
8. Wake up several times per night?	0	1	2	3	4	5
9. Have trouble staying asleep (including waking far too early)?	0	1	2	3	4	5
10. Wake up after your usual amount of sleep feeling tired and worn out?	0	1	2	3	4	5

CAM74 – Bladder Function Form (REVISED 10/09/08)
The CAM74S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6 AND field 13.

The participant completes fields 7-12 AND field 14.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-12: The participant completes these fields.

Field 13: The Study Coordinator calculates the ICSmaleIS Score.

Field 14: The participant completes this field.

Draft

CAMUS Clinical Trial
Bladder Function Form (CAM74)

Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

2. Participant ID: ☐☐☐S☐☐☐

Page Number 3. 1

4. Visit Number ☐☐ — 02=SV2.0 | 12=Week 12, 24=Week 24 | 36=Week 36, 48=Week 48 | 60=Week 60, 72=Week 72

5. Site# ☐☐☐

6. Staff ID ☐☐

This form is completed by the participant.

Instructions: *We would like to find out about your urinary symptoms and we are very grateful that you can help us by filling in this questionnaire. For each question, circle the appropriate number that best describes your condition. Please answer each question, thinking about the symptoms you have experienced in the last month. You will see that some questions ask how often you have a symptom:*

Occasionally = less than one third of the time
Sometimes = between one and two thirds of the time
Most of the time = more than two thirds of the time

In the past month how often:	Never	Occasionally	Sometimes	Most of the time	All of the time
7. Did you have to rush to the toilet to urinate?	0	1	2	3	4
8. Did urine leak before you could get to the toilet?	0	1	2	3	4
9. Did urine leak when you coughed or sneezed?	0	1	2	3	4
10. Did you leak for no obvious reason and without feeling that you wanted to go?	0	1	2	3	4
11. Did you leak urine when you were asleep?	0	1	2	3	4
12. Did you have a slight wetting of your pants a few minutes after you had finished urinating?	0	1	2	3	4

13. *To be completed by the study coordinator: ICSmaleIS Score =* ☐☐☐☐
(Total of items 7-12.)

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CAMUS Clinical Trial
Bladder Function Form (CAM74)

Participant ID
2. [ ][ ][ ]S[ ][ ][ ]

Page Number
3. 2

Visit Number
4. [ ][ ]

02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

	Very dissatisfied	Moderately dissatisfied	About equally satisfied and dissatisfied	Moderately satisfied	Very satisfied
14. If you had to spend the rest of your life with your urinary or bladder function just the way it is now, how would you feel about that?	1	2	3	4	5

CAM75 – International Prostate Symptom Score (IPSS) (REVISED 10/09/08)

This form is completed by the participant. The header information should be completed by the study coordinator.

The old forms have boxes that you place a mark in.

The new forms record actual values for all the laboratory measures.
The new forms have the codes (1, = yes, 2 = no, 3 = don't know) that should be circled.

Questions 7-13 assess the degree of discomfort BPH is causing the participant. The answers are scaled from 0 to 5, 0 indicating no discomfort and 5 indicating a lot. The AUA score is calculated by adding the scores of the answers to questions 7-13.

Questions 15 & 16 should also be completed but not included in the score.

The completion of the TPSS form completes all the requirements for the SV1.0.

Please fax completed forms to the DCC. Forms should be faxed in within 3 days of the SV1.0.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-13: These fields are completed by the participant.

Field 14: The study coordinator enters the AUASS.

Fields 15-16: These fields are completed by the participant.

Draft

CAMUS Clinical Trial
International Prostate Symptom Score (IPSS) For (CAM75)
(AUA Symptom Score & IPSS Quality of Life Questions)

1. Visit Date ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)
2. Participant ID ☐☐☐S☐☐☐
3. Page Number 1
4. Visit Number ☐☐ (01=SV1.0, 02=SV2.0, 12=Week 12, 24=Week 24, 36=Week 36, 48=Week 48, 60=Week 60, 72=Week 72)
5. Site# ☐☐☐
6. Staff ID ☐☐

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number that best describes your condition.*

	not at all	*less than 1 time in 5*	*less than half the time*	*about half the time*	*more than half the time*	*almost always*
7. Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
8. Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5
9. Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
10. Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5
11. Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5
12. Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5
	None	*1 time*	*2 times*	*3 times*	*4 times*	*5 or more times*
13. Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	0	1	2	3	4	5

14. *To be completed by the study coordinator:* *AUASS =* ☐☐☐☐ *(Total of items 7-13.)*

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CAMUS Clinical Trial
International Prostate Symptom Score (IPSS) For (CAM75)
(AUA Symptom Score & IPSS Quality of Life Questions)

Participant ID
2. [ ][ ][ ][S][ ][ ][ ]

Page Number
3. 2

Visit Number
4. [ ][ ]

01=SV1.0 02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

	Delighted	*Pleased*	*Mostly satisfied*	*Mixed-about equally satisfied and dissatisfied*	*Mostly dissatisfied*	*Unhappy*	*Terrible*
15. If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	1	2	3	4	5	6	7

	Not at all	*Less than 1 time in 5*	*Less than half the time*	*About half the time*	*More than half the time*	*Almost always*
16. Over the past month, how often when you felt the urge to urinate, did you leak urine before you could get to the toilet?	1	2	3	4	5	6

CAM77 – Subjective Global Assessment Form (REVISED 10/10/08)
The CAM77S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6.

The participant completes fields 7-10.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-10: The participant completes these fields.

Draft

CAMUS Clinical Trial
Subjective Global Assessment Form (CAM77)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (24=Week 24, 48=Week 48, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number that best describes your urinary symptoms.*

	Much Better	*Somewhat better*	*A little better*	*About the same*	*A little worse*	*Somewhat worse*	*Much worse*
7. Compared to the beginning of the study, how are your urinary symptoms now?	1	2	3	4	5	6	7
8. Compared to the beginning of the study, how are your urinary incontinence symptoms now?	1	2	3	4	5	6	7

	Very satisfied	*Somewhat satisfied*	*Neither satisfied nor dissatisfied*	*Somewhat dissatisfied*	*Very dissatisfied*
9. How satisfied or dissatisfied are you with any urinary symptoms you have now?	1	2	3	4	5
10. How satisfied or dissatisfied are you with any urinary incontinence symptoms you have now?	1	2	3	4	5

CAM79 – Participant Treatment Perception Form (REVISED 10/10/08)
The CAM79S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6.

The participant completes fields 7.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7: The participant completes this field.

Draft

CAMUS Clinical Trial
Participant Treatment Perception Form (CAM79)

1. Visit Date ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)

2. Participant ID ☐☐☐S☐☐☐

3. Page Number 1

4. Visit Number ☐☐ (24=Week 24, 48=Week 48, 72=Week 72)

5. Site# ☐☐☐

6. Staff ID ☐☐

Question 7 is to be completed at every 24, 48, and 72 weeks.

Circle the appropriate number

	I am not sure which treatement I am getting	*I think I am getting the placebo pills (no active treatement)*	*I think I am getting the Saw palmetto plant extract*	*I am not taking any CAMUS pills right now*
7. What is your best guess about what treatment you are getting as part of the CAMUS study?	1	2	3	4

CAM81 – Adverse Event Form (REVISED 10/13/08)

An adverse event is an unexpected medical problem that happens during treatment with a drug or other therapy. Adverse events do not have to be caused by the drug or therapy, and they may be mild, moderate, or severe. **All adverse events, regardless of severity, and whether or not ascribed to the study drug administration, should be recorded on CAM81.** All grade 3, 4 and 5 adverse events will be reviewed by the Clinical Review Committee.

Please refer to the document entitled 'SAE reporting Guidelines' provided by the American College of Surgeons – Oncology Group in the Appendix, for more details on the grading SAEs, attributing causes to SAEs and reporting of SAEs.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not the participant has experienced an adverse event since the last visit.

If yes, complete fields 8-18. (An additional event can be reported in fields 9-29.) Please refer to the table at the bottom of the page for applicable codes.

Draft

CAMUS Clinical Trial
Adverse Event Form (CAM81)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: ☐
4. Visit Number: ☐☐

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

5. Site#: ☐☐☐
6. Staff ID: ☐☐

Circle the appropriate number

	Yes	No	
7. Has the participant experienced an adverse event since the last visit ?	1	2	⇨ If "Yes", record below. ⇨ If "No", stop here.

8. **MEDDRA Code:** ☐☐☐☐☐☐☐☐
9. **Description:** _____

Date of Onset: (mm dd yyyy) **Continuing** ☐ **OR** **Date Resolved:** (mm dd yyyy)

10. ☐☐/☐☐/☐☐☐☐ ☐ **OR** 11. ☐☐/☐☐/☐☐☐☐

12. **Serious?** ☐ No ☐ Yes ⇨ *Complete SAE Form (CAM82)* **13. Severity** *(See Codes):* ☐
14. **Relationship to Study** *(See Codes):* ☐ **15. Outcome** *(See Codes):* ☐ **16. Anticipated?** ☐ No ☐ Yes
17. **Action Taken** 1 2 3 4 5 6 *(See Codes & circle all that apply):* **18. Action Taken Regarding Study Drug** *(See Codes):* ☐
19. **MEDDRA Code:** ☐☐☐☐☐☐☐☐
20. **Description:** _____

Date of Onset: (mm dd yyyy) **Continuing** ☐ **OR** **Date Resolved:** (mm dd yyyy)

21. ☐☐/☐☐/☐☐☐☐ ☐ **OR** 22. ☐☐/☐☐/☐☐☐☐

23. **Serious?** ☐ No ☐ Yes ⇨ *Complete SAE Form (CAM82)* **24. Severity** *(See Codes):* ☐
25. **Relationship to Study** *(See Codes):* ☐ **26. Outcome** *(See Codes):* ☐ **27. Anticipated?** ☐ No ☐ Yes
28. **Action Taken** 1 2 3 4 5 6 *(See Codes & circle all that apply):* **29. Action Taken Regarding Study Drug** *(See Codes):* ☐

Relationship to Study Codes: (1) Unrelated, (2) Unlikely, (3) Possible, (4) Probable, (5) Definite

Severity: (1) Mild, (2) Moderate, (3) Severe, (4) Life Threatening, (5) Death

Outcome Codes: (1) Complete recovery w/o residual effect, (2) Recovered w/ residual effect, (3) Recovered w/ persistent effect, (4) Not yet recovered, (5) Died

Action Taken Codes: (1) Self or OTC treatment, (2) Office, clinic, ER, or out-pt visit, (3) In-pt visit or hosp admit, (4) Rx, (5) Procedure performed, (6) None

Action Taken Regarding Study Drug Codes: (0) Not applicable, (1) None, (2) Reduced, (3) Interrupted, (4) Discontinued

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FORMS REQUIRED FOR VISITS FOR WEEKS 12, 24, 36, 48 and 60

CAM Form	Procedure	Filled by
22	Medical Follow-Up	Study Coordinator
23/24	Assessment of Medicine	Study Coordinator
31	Vital Signs	Study Coordinator
41	PSA	Study Coordinator
42	Uroflow Measurement	Study Coordinator
45	Hematology and EKG	Study Coordinator
46	Urinalysis	Study Coordinator
47	Serum Banking	Study Coordinator
71	Jenkins Sleep Dysfunction Scale	Participant
74	Bladder Function	Participant
75	International Prostate Symptom Score (IPSS)	Participant
77	Subject Global Assessment	Participant
79	Participant Treatment Perception Form	Participant
81	Adverse Events	Study Coordinator

CAM22 – History Update Form (REVISED 10/10/08)

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number.

Field 6: Enter the initials of the staff person completing the form.

Fields 7-12: The study coordinator completes these fields and also completes additional forms as directed by the answers provided.

Draft

CAMUS Clinical Trial
History Update Form (CAM22)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

2. Participant ID: ☐☐☐S☐☐☐

3. Page Number: 1

4. Visit Number: ☐☐

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

5. Site#: ☐☐☐

6. Staff ID: ☐☐

Circle the appropriate number	Yes	No	Don't Know
7. Have there been changes in or new concomitant medications since the last visit? **⇨ If yes, update concomitant medication form (CAM23).**	1	2	3
8. Have there been changes in or new urology medications since the last visit? **⇨ If yes, update urology medication tracking form (CAM24).**	1	2	3
9. Has the participant experienced any new adverse events since the last visit? **⇨ If yes, update adverse events form (CAM81).**	1	2	3
10. Have previously reported adverse events resolved or worsened since the last visit ? **⇨ If yes, update adverse events form (CAM81).**	1	2	3
11. Does participant currently have a suprapubic catheter, use CIC/ISC, or had a catheter removed since the last visit?	1	2	3
12. Has the participant reached a protocol defined BPH outcome? **⇨ If yes, update BPH outcome events form (CAM61).**	1	2	3

CAM23 – Concomitant Medication Form (REVISED 10/13/08)

Two separate medications can be reported on one form. For additional medications, please use an additional CAM23 and enter the page number in field 3.

Since the number of pages required for these forms will vary with the patient, page numbers have been omitted from these headers. Please be sure to fill in the page number along with other header information.

Do not duplicate medications listed on the Urology Medication Tracking Form (CAM 24).

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: If SV1, indicate whether or not the participant has taken any medications during the last 6 months. If this is not SV1, indicate whether or not the participant has started or stopped any urology medications since the last visit. **If yes, complete fields 8-23.**

Field 8: Enter the generic name of the medication.

Field 9: Enter the total dosage.

Field 10: Enter the dosage units. Refer to the dosage unit codes at the bottom of the form.

Field 11: Enter the frequency of dose. Refer to the frequency codes at the bottom of the form.

Field 12: Enter the mode of administration. Refer to the mode of administration codes at the bottom of the form.

Field 13: Enter the date the medication was started.

Field 14: Enter the date the medication was stopped **OR** check “Ongoing”.

Field 15: Indicate the primary reason for use or change.

Draft

CAMUS Clinical Trial
Concomitant Medication Form (CAM23)

1. Visit Date: mm / dd / yyyy
2. Participant ID: S
3. Page Number
4. Visit Number: 01=SV1.0; 04=Week 4, 12=Week 12, 24=Week 24; 28=Week 28, 36=Week 36, 48=Week 48; 52=Week 52, 60=Week 60, 72=Week 72
5. Site#
6. Staff ID

Do not duplicate medications listed on the Urology Medication Tracking Form (CAM24). Number page(s) in upper right corner of the form.

Circle the appropriate number

	Yes	No	Don't Know
	1	2	3

7. If this is screening visit 1, has the participant taken any medications during the last 6 months? If this is not screening visit 1, since the last visit, has the participant started or stopped any medications ?
   ⇨ **If "Yes", continue to complete below.**
   ⇨ **If "No", stop here.**

8. **Medication** *(Give generic name):* _____

9. **Total Dosage:** _____
10. **Dosage Units** *(See Codes below)* ☐ ⇨ If "other", Specify: _____
11. **Frequency** *(See Codes below)* ☐ ⇨ If "other", Specify: _____
12. **Mode of Administration** *(See Codes below)* ☐ ⇨ If "other", Specify: _____
13. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐
    Ongoing: ☐ *Or* ⇨
14. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐
15. **Primary Reason for Use or Change:** _____

16. **Medication** *(Give generic name):* _____

17. **Total Dosage:** _____
18. **Dosage Units** *(See Codes below)* ☐ ⇨ If "other", Specify: _____
19. **Frequency** *(See Codes below)* ☐ ⇨ If "other", Specify: _____
20. **Mode of Administration** *(See Codes below)* ☐ ⇨ If "other", Specify: _____
21. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐
    Ongoing: ☐ *Or* ⇨
22. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐
23. **Primary Reason for Use or Change:** _____

Dosage Units Codes: **(1)** mg, **(2)** mcg or ug, **(3)** ml or cc, **(4)** units, **(5)** g, **(6)** Other (specify)

Frequency Codes: **(1)** Single Dose, **(2)** BID, **(3)** TID, **(4)** QID, **(5)** PRN, **(6)** Q4h, **(7)** Other (specify)

Mode of Administration Codes: **(1)** Intravenous, **(2)** Oral, (3) Intra-muscular, **(4)** Sub-lingual, **(5)** Intra-urethral, **(6)** Patches, **(7)** Other (specify)

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[redacted]
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CAM24 – Urology Medication Tracking Form (REVISED 10/13/08)

Two separate medications can be reported on one form. For additional medications, please use an additional CAM24 and enter the page number in field 3.

Since the number of pages required for these forms will vary with the patient, page numbers have been omitted from these headers. Please be sure to fill in the page number along with other header information.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: If SV1, indicate whether or not the participant has taken any urology medications during the last 6 months. If this is not SV1, indicate whether or not the participant has started or stopped any urology medications since the last visit. **If yes, complete fields 8-21.**

Field 8: Enter the generic name of the medication.

Field 9: Enter the total dosage.

Field 10: Enter the dosage units. Refer to the dosage unit codes at the bottom of the form.

Field 11: Enter the frequency of dose. Refer to the frequency codes at the bottom of the form.

Field 12: Enter the mode of administration. Refer to the mode of administration codes at the bottom of the form.

Field 13: Enter the date the medication was started.

Field 14: Enter the date the medication was stopped **OR** check “Ongoing”.

Draft

CAMUS Clinical Trial
Urology Medication Tracking Form (CAM24)

1. Visit Date ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

2. Participant ID ☐☐☐S☐☐☐

3. Page Number ☐

4. Visit Number ☐☐

01=SV1.0	04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

5. Site# ☐☐☐

6. Staff ID ☐☐

Do not duplicate medications listed on the Concomitant Medication Form (CAM23). Number page(s) in upper right corner of the form.

Circle the appropriate number

	Yes	No	Don't Know
7. If this is screening visit 1, has the participant taken any urology medications during the last 6 months? If this is not screening visit 1, since the last visit, has the participant started or stopped any urology medications?	1	2	3

⇨ **If "Yes", continue to complete below.**

⇨ **If "No", stop here.**

8. **Medication** *(Give generic name):* _____

9. **Total Dosage:** _____

10. **Dosage Units** ☐ ⇨ If "other", Specify: _____
(See Codes below)

11. **Frequency** *(See Codes below)* ☐ ⇨ If "other", Specify: _____

12. **Mode of Administration** *(See Codes below)* ☐ ⇨ If "other", Specify: _____

13. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨

14. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

15. **Medication** *(Give generic name):* _____

16. **Total Dosage:** _____

17. **Dosage Units** ☐ ⇨ If "other", Specify: _____
(See Codes below)

18. **Frequency** *(See Codes below)* ☐ ⇨ If "other", Specify: _____

19. **Mode of Administration** *(See Codes below)* ☐ ⇨ If "other", Specify: _____

20. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨

21. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

Dosage Units Codes: **(1)** mg, **(2)** mcg or ug, **(3)** ml or cc, **(4)** units, **(5)** g, **(6)** Other (specify)

Frequency Codes: **(1)** Single Dose, **(2)** BID, **(3)** TID, **(4)** QID, **(5)** PRN, **(6)** Q4h, **(7)** Other (specify)

Mode of Administration Codes: **(1)** Intravenous, **(2)** Oral, (3) Intra-muscular, **(4)** Sub-lingual, **(5)** Intra-urethral, **(6)** Patches, **(7)** Other (specify)

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CAM 31 – Vital Signs Form (REVISED 10/10/08)

The old forms for this study ask for the BP to be taken both lying down and standing.

For this study, you only need to take two consecutive measurements five minutes apart, both sitting down

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the 3-digit site number.

Field 4: This field is pre-filled.

Field 5: Enter the visit number. Refer to the table.

Field 6: Enter the initials of the staff person completing the form.

Field 7: Check the appropriate visit type.

The vital signs have to be recorded at the first screening visit or the second visit.

Field 8: Indicate whether or not vital signs were obtained. If yes, complete questions 9-11.

Draft

CAMUS Clinical Trial
Vital Signs Form (CAM31)

Visit Date 1. ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)

2. Participant ID ☐☐☐S☐☐☐

3. Site# ☐☐☐

Page Number 4. 1

Visit Number 5. ☐☐

01=SV1.0	04=Week 4	28=Week 28	52=Week 52
02=SV2.0	12=Week 12	36=Week 36	60=Week 60
	24=Week 24	48=Week 48	72=Week 72

Staff ID 6. ☐☐

Visit type 7. ☐ In-Clinic Visit ☐ Telephone Interview

Circle the appropriate number	Yes	No
8. Were vital signs done at this visit? ⇨ **If "No", stop here. If "Yes", record below.**	1	2

9. Height: ☐☐ inches (In-Clinic Only)

10. Weight: ☐☐☐ pounds (In-Clinic Only)

11. Seated measurements (reading 1 taken immediately, reading 2 taken 1 minute later):

(a) Blood pressure reading 1 ☐☐☐ (Systolic) / ☐☐☐ (Diastolic) mm Hg

(b) Heart rate reading 1 ☐☐☐ bpm

(c) Time of Day 1 ☐☐☐☐ ☐ AM ☐ PM

(d) Blood pressure reading 2 ☐☐☐ (Systolic) / ☐☐☐ (Diastolic) mm Hg

(e) Heart rate reading 2 ☐☐☐ bpm

CAM41 – PSA Sample Collection (REVISED 10/10/08)

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

A PSA level above 10ng/ml is an exclusionary criterion.

All PSA levels for the study are done at the same laboratory. The blood sample has to be collected and sent to the laboratory as set forth in the section on sample collection.

When the PSA level comes back, it is recorded on this same form.

In the old forms where there is only one decimal place, please just record the first number after the decimal. **There is no need to round up or down**.

Field 7: Indicate whether or not a serum PSA sample was collected. If yes, record the date of collection and complete fields 8-10.

Field 8: Indicate whether or not the serum PSA sample was shipped to central lab.

Field 9: Record the date of shipment.

Field 10: Record the PSA results.

[redacted] [redacted] Draft

CAMUS Clinical Trial
PSA Sample Collection (CAM41)

1. Visit Date: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0; 24=Week 24, 48=Week 48, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

Circle the appropriate number

Serum PSA:	**Yes**	**No**
7. Was a serum PSA sample collected at this visit?	1	2

⇨ If "Yes", record date of collection: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)

⇨ If "No", STOP.

	Yes	**No**
8. *Was a serum PSA sample shipped to central lab?	1	2

9. *If "Yes", record the date of shipment: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)

10. PSA results from Central Lab: ☐☐.☐☐ ng/ml

For screening visit 1, excluded if serum prostate specific antigen level > 10 ng/ml.

**Does not apply to site# 277*

CAM42 – Uroflow Measurement Form (REVISED 10/10/08)

This form records information from the Uroflow tests.

Peak flow rate < 4 ml/sec and voided volume < 125 ml are both exclusionary criteria.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not uroflow measurements were obtained. If yes, complete fields 8-14.

Draft

CAMUS Clinical Trial
Uroflow Measurement Form (CAM42)

Visit Date: ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)

Participant ID: 2. ☐☐☐S☐☐☐

Page Number: 3. 1

Visit Number: ☐☐

01=SV1.0 02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

Site#: 5. ☐☐☐

Staff ID: 6. ☐☐

Circle the appropriate number	Yes	No
7. Were uroflow measurements done at this visit?	1	2

⇨ **If "No", stop here.**
If "Yes", record below.

8. Voiding time: ☐☐☐ sec

9. Flow time: ☐☐☐ sec

10. Time to maximum flow: ☐☐☐ sec

11. Peak flow rate: ☐☐.☐☐ ml/sec

For screening visits 1 and 2: Excluded if peak flow rate is less than 4 ml/sec.

12. Mean flow rate: ☐☐.☐☐ ml/sec

13. Voided volume: ☐☐☐☐ ml

For screening visits: Excluded if voided volume < 125 ml.

14. Post-void residual: ☐☐☐ ml

CAM45 – CBC, Serum Chemistries, Prothrombin Time and EKG Form (REVISED 10/14/08)

The old forms only ask if the values were normal or abnormal.
The old forms have boxes that you place a mark in.

The new forms record actual values for all the laboratory measures.
The new forms have the codes (1, = yes, 2 = no, 3 = don't know) that should be circled.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a complete blood count was obtained. If yes, complete a-e.

Field 8: Record the prothrombin time.

Field 9: Indicate whether or not a serum chemistry panel was obtained. If yes, complete a-i.

Field 10: For baseline, 24, 48 and 72 week visits, indicate whether or not an EKG was performed.

Recording whether an EKG is normal or abnormal with respect to recent MI or active Ischemia should be based on a Final report from a cardiologist.

All attempts should be made to ensure that these reports are received in a timely manner, so that the second screening visit and randomization visits can be scheduled in a timely fashion.

If any values are abnormal, complete the adverse events form (CAM81).

Draft

CAMUS Clinical Trial
CBC, Serum Chemistries, Prothrombin Time and EKG Form (CAM45)

1. Visit Date: ___ / ___ / ____ (mm / dd / yyyy)
2. Participant ID: ____ S ___
3. Page Number: 1
4. Visit Number: ___ (01=SV1.0; 12=Week 12, 24=Week 24; 36=Week 36, 48=Week 48; 60=Week 60, 72=Week 72)
5. Site#: ___
6. Staff ID: ___

Circle the appropriate number

7. Complete blood count:

	Yes	No
Was a complete blood count done at this visit?	1	2

If "No", skip to question 8. If "Yes", record below.

		Normal	Abnormal	Not Done
(a) Leukocyte count (WBC):	___.___ thou/cmm	1	2	3
(b) Erythrocyte count (RBC):	___.___ mill/cmm	1	2	3
(c) Hemoglobin:	___.___ g/dl	1	2	3
(d) Hematocrit:	___.___ %	1	2	3
(e) Platelet count:	___.___ thou/cmm	1	2	3

If any values are abnormal, complete adverse events form (CAM81).

8. Prothrombin time:

___.___ **Seconds** ___.___ **Upper limit of normal or control value (Seconds)** **INR:** ___.___

9. Serum chemistries:

	Yes	No
Was a serum chemistry panel done at this visit?	1	2

If "No", stop. If "Yes", record below.

		Normal	Abnormal	Not Done
(a) Sodium:	___.___ meq/l	1	2	3
(b) Potassium:	___.___ meq/l	1	2	3
(c) Chloride:	___.___ meq/l	1	2	3
(d) Bicarbonate:	___.___ meq/l	1	2	3
(e) Glucose:	___.___ meq/l	1	2	3
(f) Creatinine	___.___ meq/l	1	2	3
(g) ALT (SGPT):	___.___ IU/L	1	2	3
(h) AST (SGOT):	___.___ IU/L	1	2	3
(i) GGT:	___.___ IU/L	1	2	3

8. Complete this section every Baseline, 24, 48 and 72 week visit only.

Electrocardiogram:	1	2	3

If any values are abnormal, complete adverse events form (CAM81).

CAM46 – Urinalysis Form (REVISED 10/10/08)

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a urinalysis was performed. If yes, complete fields 8-9

Field 8: Record the results based on the dipstick test.

Field 9: Record the results based on the microscopic urinalysis.

Draft

CAMUS Clinical Trial
Urinalysis Form (CAM46)

1. Visit Date ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID ☐☐☐S☐☐☐
3. Page Number 1
4. Visit Number ☐☐ (01=SV1.0, 72=Week 72)
5. Site# ☐☐☐
6. Staff ID ☐☐

Circle the appropriate number	Yes	No
7. Was an urinalysis done at this visit?	1	2

⇨ **If "Yes", record the results below.**

⇨ **If "No", stop.**

(8) Dipstick

(a) pH: ☐.☐

	0	*trace*	*1+*	*2+*	*3+*	*4+*
(b) Glucose	1	2	3	4	5	6
(c) Blood	1	2	3	4	5	6
(d) Ketones	1	2	3	4	5	6
(e) Protein	1	2	3	4	5	6
(f) Leukocyte esterase	1	2	3	4	5	6

(9) If dipstick is positive (> 0) for blood or leukocyte esterase, send specimen for microscopic urinalysis and code results below.

	none, negative, WNL	*1-5, trace, present, slight, rare*	*6-15, moderate*	*16-30, many, frequent*	*>30, innumerable, TNTC*
(a) WBC	1	2	3	4	5
(b) RBC	1	2	3	4	5
(c) Epithelial cells	1	2	3	4	5
(d) Mucous	1	2	3	4	5
(e) Bacteria	1	2	3	4	5
(f) Casts hyaline	1	2	3	4	5
(g) Casts other	1	2	3	4	5

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Toll Number: (205) 975-7453

CAM47 – Serum for Banking Form (REVISED 10/10/08)

If the patient has consented to it, a serum sample from the patient collected at the first visit and the separation visit is to be sent to the NIDDK repository. The samples are being collected and stored for future ancillary studies.

This form is used to identify patients whose sample is collected during SV1.0 and sent to the NIDDK.

If no sample is collected, the reasons for not collecting are also recorded.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a serum sample was collected.

Field 8: Enter the date of collection if applicable.

Field 9: Indicate the reason specimens were not obtained if applicable.

Field 10: Indicate whether or not the sample was shipped.

Field 11: Enter the date of shipment if applicable.

Draft

CAMUS Clinical Trial
Serum for Banking Form (CAM47)

1. Visit Date: ☐☐ / ☐☐ / ☐☐☐☐ (mm / dd / yyyy)

2. Participant ID: ☐☐☐S☐☐☐

3. Page Number: 1

4. Visit Number: ☐☐ (01=SV1.0, 72=Week 72)

5. Site#: ☐☐☐

6. Staff ID: ☐☐

Circle the appropriate number

	Yes	No
7. Was a serum sample collected at this visit?	1	2

8. If "Yes", Date of collection: ☐☐ / ☐☐ / ☐☐☐☐ (mm / dd / yyyy)

9. If specimens were not obtained for CAMUS, please indicate reason (Check only one).

☐ (1)Patient refused to give informed consent for CAMUS serum studies (banking).

☐ (2)Patient was not asked to consider CAMUS serum studies (banking).

☐ (3)Other, specify: _____

	Yes	No
10. Was a serum sample shipped to NIDDK repository?	1	2

11. If "Yes", record the date of shipment: ☐☐ / ☐☐ / ☐☐☐☐ (mm / dd / yyyy)

CAM71 – Jenkins Sleep Dysfunction Scale Form (REVISED 10/10/08)
The CAM71S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6.

The participant completes fields 7-10.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-10: The participant completes these fields.

Draft

CAMUS Clinical Trial
Jenkins Sleep Dysfunction Scale Form (CAM71)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (03=Baseline; 24=Week 24, 48=Week 48, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number that best describes your condition.*

In the past month, how often did you:

	not at all	*1-3 days*	*4-7 days*	*8-14 days*	*15-21 days*	*22-31 days*
7. Have trouble falling asleep?	0	1	2	3	4	5
8. Wake up several times per night?	0	1	2	3	4	5
9. Have trouble staying asleep (including waking far too early)?	0	1	2	3	4	5
10. Wake up after your usual amount of sleep feeling tired and worn out?	0	1	2	3	4	5

CAM74 – Bladder Function Form (REVISED 10/09/08)
The CAM74S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6 AND field 13.

The participant completes fields 7-12 AND field 14.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-12: The participant completes these fields.

Field 13: The Study Coordinator calculates the ICSmaleIS Score.

Field 14: The participant completes this field.

Draft

CAMUS Clinical Trial
Bladder Function Form (CAM74)

Visit Date: ___/___/____ (mm/dd/yyyy)

Participant ID: 2. ____S____

Page Number: 3. 1

Visit Number: 4. ____ (02=SV2.0; 12=Week 12, 24=Week 24; 36=Week 36, 48=Week 48; 60=Week 60, 72=Week 72)

Site#: 5. ____

Staff ID: 6. ____

This form is completed by the participant.

Instructions: *We would like to find out about your urinary symptoms and we are very grateful that you can help us by filling in this questionnaire. For each question, circle the appropriate number that best describes your condition. Please answer each question, thinking about the symptoms you have experienced in the last month. You will see that some questions ask how often you have a symptom:*

Occasionally = less than one third of the time
Sometimes = between one and two thirds of the time
Most of the time = more than two thirds of the time

In the past month how often:	Never	Occasionally	Sometimes	Most of the time	All of the time
7. Did you have to rush to the toilet to urinate?	0	1	2	3	4
8. Did urine leak before you could get to the toilet?	0	1	2	3	4
9. Did urine leak when you coughed or sneezed?	0	1	2	3	4
10. Did you leak for no obvious reason and without feeling that you wanted to go?	0	1	2	3	4
11. Did you leak urine when you were asleep?	0	1	2	3	4
12. Did you have a slight wetting of your pants a few minutes after you had finished urinating?	0	1	2	3	4

13. *To be completed by the study coordinator:* *ICSmaleIS Score =* ____ *(Total of items 7-12.)*

Draft

CAMUS Clinical Trial
Bladder Function Form (CAM74)

Participant ID
2. [ ][ ][ ]S[ ][ ][ ]

Page Number
3. 2

Visit Number
4. [ ][ ]

02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

	Very dissatisfied	Moderately dissatisfied	About equally satisfied and dissatisfied	Moderately satisfied	Very satisfied
14. If you had to spend the rest of your life with your urinary or bladder function just the way it is now, how would you feel about that?	1	2	3	4	5

CAM75 – International Prostate Symptom Score (IPSS) (REVISED 10/09/08)

This form is completed by the participant. The header information should be completed by the study coordinator.

The old forms have boxes that you place a mark in.

The new forms record actual values for all the laboratory measures.
The new forms have the codes (1, = yes, 2 = no, 3 = don't know) that should be circled.

Questions 7-13 assess the degree of discomfort BPH is causing the participant. The answers are scaled from 0 to 5, 0 indicating no discomfort and 5 indicating a lot. The AUA score is calculated by adding the scores of the answers to questions 7-13.

Questions 15 & 16 should also be completed but not included in the score.

The completion of the TPSS form completes all the requirements for the SV1.0.

Please fax completed forms to the DCC. Forms should be faxed in within 3 days of the SV1.0.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-13: These fields are completed by the participant.

Field 14: The study coordinator enters the AUASS.

Fields 15-16: These fields are completed by the participant.

Draft

CAMUS Clinical Trial
International Prostate Symptom Score (IPSS) For (CAM75)
(AUA Symptom Score & IPSS Quality of Life Questions)

1. Visit Date: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0, 02=SV2.0, 12=Week 12, 24=Week 24, 36=Week 36, 48=Week 48, 60=Week 60, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number that best describes your condition.*

	not at all	*less than 1 time in 5*	*less than half the time*	*about half the time*	*more than half the time*	*almost always*
7. Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
8. Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5
9. Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
10. Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5
11. Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5
12. Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5
	None	*1 time*	*2 times*	*3 times*	*4 times*	*5 or more times*
13. Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	0	1	2	3	4	5

14. *To be completed by the study coordinator:* *AUASS =* ☐☐☐☐ *(Total of items 7-13.)*

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Toll Number: (205) 975-7453

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CAMUS Clinical Trial
International Prostate Symptom Score (IPSS) For (CAM75)
(AUA Symptom Score & IPSS Quality of Life Questions)

Participant ID
2. [ ][ ][ ][S][ ][ ][ ]

Page Number
3. [2]

Visit Number
4. [ ][ ]

01=SV1.0 02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

	Delighted	*Pleased*	*Mostly satisfied*	*Mixed-about equally satisfied and dissatisfied*	*Mostly dissatisfied*	*Unhappy*	*Terrible*
15. If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	1	2	3	4	5	6	7

	Not at all	*Less than 1 time in 5*	*Less than half the time*	*About half the time*	*More than half the time*	*Almost always*
16. Over the past month, how often when you felt the urge to urinate, did you leak urine before you could get to the toilet?	1	2	3	4	5	6

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Toll Number: (205) 975-7453

CAM77 – Subjective Global Assessment Form (REVISED 10/10/08)
The CAM77S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6.

The participant completes fields 7-10.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-10: The participant completes these fields.

Draft

CAMUS Clinical Trial
Subjective Global Assessment Form (CAM77)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (24=Week 24, 48=Week 48, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number that best describes your urinary symptoms.*

	Much Better	*Somewhat better*	*A little better*	*About the same*	*A little worse*	*Somewhat worse*	*Much worse*
7. Compared to the beginning of the study, how are your urinary symptoms now?	1	2	3	4	5	6	7
8. Compared to the beginning of the study, how are your urinary incontinence symptoms now?	1	2	3	4	5	6	7

	Very satisfied	*Somewhat satisfied*	*Neither satisfied nor dissatisfied*	*Somewhat dissatisfied*	*Very dissatisfied*
9. How satisfied or dissatisfied are you with any urinary symptoms you have now?	1	2	3	4	5
10. How satisfied or dissatisfied are you with any urinary incontinence symptoms you have now?	1	2	3	4	5

CAM79 – Participant Treatment Perception Form (REVISED 10/10/08)
The CAM79S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6.

The participant completes fields 7.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7: The participant completes this field.

Draft

CAMUS Clinical Trial
Participant Treatment Perception Form (CAM79)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (24=Week 24, 48=Week 48, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

Question 7 is to be completed at every 24, 48, and 72 weeks.

Circle the appropriate number

	I am not sure which treatement I am getting	*I think I am getting the placebo pills (no active treatement)*	*I think I am getting the Saw palmetto plant extract*	*I am not taking any CAMUS pills right now*
7. What is your best guess about what treatment you are getting as part of the CAMUS study?	1	2	3	4

CAM81 – Adverse Event Form (REVISED 10/13/08)

An adverse event is an unexpected medical problem that happens during treatment with a drug or other therapy. Adverse events do not have to be caused by the drug or therapy, and they may be mild, moderate, or severe. **All adverse events, regardless of severity, and whether or not ascribed to the study drug administration, should be recorded on CAM81.** All grade 3, 4 and 5 adverse events will be reviewed by the Clinical Review Committee.

Please refer to the document entitled 'SAE reporting Guidelines' provided by the American College of Surgeons – Oncology Group in the Appendix, for more details on the grading SAEs, attributing causes to SAEs and reporting of SAEs.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not the participant has experienced an adverse event since the last visit.

If yes, complete fields 8-18. (An additional event can be reported in fields 9-29.) Please refer to the table at the bottom of the page for applicable codes.

Draft

CAMUS Clinical Trial
Adverse Event Form (CAM81)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: ☐
4. Visit Number: ☐☐

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

5. Site#: ☐☐☐
6. Staff ID: ☐☐

Circle the appropriate number

	Yes	No	
7. Has the participant experienced an adverse event since the last visit ?	1	2	⇨ If "Yes", record below. ⇨ If "No", stop here.

8. **MEDDRA Code:** ☐☐☐☐☐☐☐☐

9. **Description:** _____

10. **Date of Onset:** ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy) **Continuing** ☐ **OR** 11. **Date Resolved:** ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)

12. **Serious?** ☐ No ☐ Yes ⇨ *Complete SAE Form (CAM82)* 13. **Severity** *(See Codes):* ☐

14. **Relationship to Study** *(See Codes):* ☐ 15. **Outcome** *(See Codes):* ☐ 16. **Anticipated?** ☐ No ☐ Yes

17. **Action Taken** 1 2 3 4 5 6 *(See Codes & circle all that apply):* 18. **Action Taken Regarding Study Drug** *(See Codes):* ☐

19. **MEDDRA Code:** ☐☐☐☐☐☐☐☐

20. **Description:** _____

21. **Date of Onset:** ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy) **Continuing** ☐ **OR** 22. **Date Resolved:** ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)

23. **Serious?** ☐ No ☐ Yes ⇨ *Complete SAE Form (CAM82)* 24. **Severity** *(See Codes):* ☐

25. **Relationship to Study** *(See Codes):* ☐ 26. **Outcome** *(See Codes):* ☐ 27. **Anticipated?** ☐ No ☐ Yes

28. **Action Taken** 1 2 3 4 5 6 *(See Codes & circle all that apply):* 29. **Action Taken Regarding Study Drug** *(See Codes):* ☐

Relationship to Study Codes: (1) Unrelated, (2) Unlikely, (3) Possible, (4) Probable, (5) Definite

Severity: (1) Mild, (2) Moderate, (3) Severe, (4) Life Threatening, (5) Death

Outcome Codes: (1) Complete recovery w/o residual effect, (2) Recovered w/ residual effect, (3) Recovered w/ persistent effect, (4) Not yet recovered, (5) Died

Action Taken Codes: (1) Self or OTC treatment, (2) Office, clinic, ER, or out-pt visit, (3) In-pt visit or hosp admit, (4) Rx, (5) Procedure performed, (6) None

Action Taken Regarding Study Drug Codes: (0) Not applicable, (1) None, (2) Reduced, (3) Interrupted, (4) Discontinued

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Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

FORMS REQUIRED FOR WEEK 72

CAM Form	Procedure	Completed By
22	Medical Follow-Up	Study Coordinator
23/24	Assessment of Medicine	Study Coordinator
31	Vital Signs	Study Coordinator
41	PSA	Study Coordinator
42	Uroflow Measurement	Study Coordinator
45	Hematology and EKG	Study Coordinator
46	Urinalysis	Study Coordinator
47	Serum Banking	Study Coordinator
62	Permanent Discontinuation of CAMUS Study	Study Coordinator
71	Jenkins Sleep Dysfunction Scale	Participant
74	Bladder Function	Paticipant
75	International Prostate Symptom Score (IPSS)	Participant
77	Subject Global Assessment	Participant
79	Participant Treatment Perception Form	Participant
81	Adverse Events	Study Coordinator

CAM22 – History Update Form (REVISED 10/10/08)

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number.

Field 6: Enter the initials of the staff person completing the form.

Fields 7-12: The study coordinator completes these fields and also completes additional forms as directed by the answers provided.

Draft

CAMUS Clinical Trial
History Update Form (CAM22)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)

2. Participant ID: ☐☐☐S☐☐☐

3. Page Number: 1

4. Visit Number: ☐☐

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

5. Site#: ☐☐☐

6. Staff ID: ☐☐

Circle the appropriate number	Yes	No	Don't Know
7. Have there been changes in or new concomitant medications since the last visit? ⇨ **If yes, update concomitant medication form (CAM23).**	1	2	3
8. Have there been changes in or new urology medications since the last visit? ⇨ **If yes, update urology medication tracking form (CAM24).**	1	2	3
9. Has the participant experienced any new adverse events since the last visit? ⇨ **If yes, update adverse events form (CAM81).**	1	2	3
10. Have previously reported adverse events resolved or worsened since the last visit ? ⇨ **If yes, update adverse events form (CAM81).**	1	2	3
11. Does participant currently have a suprapubic catheter, use CIC/ISC, or had a catheter removed since the last visit?	1	2	3
12. Has the participant reached a protocol defined BPH outcome? ⇨ **If yes, update BPH outcome events form (CAM61).**	1	2	3

CAM23 – Concomitant Medication Form (REVISED 10/13/08)

Two separate medications can be reported on one form. For additional medications, please use an additional CAM23 and enter the page number in field 3.

Since the number of pages required for these forms will vary with the patient, page numbers have been omitted from these headers. Please be sure to fill in the page number along with other header information.

Do not duplicate medications listed on the Urology Medication Tracking Form (CAM 24).

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: If SV1, indicate whether or not the participant has taken any medications during the last 6 months. If this is not SV1, indicate whether or not the participant has started or stopped any urology medications since the last visit. **If yes, complete fields 8-23.**

Field 8: Enter the generic name of the medication.

Field 9: Enter the total dosage.

Field 10: Enter the dosage units. Refer to the dosage unit codes at the bottom of the form.

Field 11: Enter the frequency of dose. Refer to the frequency codes at the bottom of the form.

Field 12: Enter the mode of administration. Refer to the mode of administration codes at the bottom of the form.

Field 13: Enter the date the medication was started.

Field 14: Enter the date the medication was stopped **OR** check “Ongoing”.

Field 15: Indicate the primary reason for use or change.

Draft

CAMUS Clinical Trial
Concomitant Medication Form (CAM23)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: ☐
4. Visit Number: ☐☐

01=SV1.0	04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

5. Site#: ☐☐☐
6. Staff ID: ☐☐

Do not duplicate medications listed on the Urology Medication Tracking Form (CAM24). Number page(s) in upper right corner of the form.

Circle the appropriate number

	Yes	No	Don't Know
	1	2	3

7. If this is screening visit 1, has the participant taken any medications during the last 6 months? If this is not screening visit 1, since the last visit, has the participant started or stopped any medications ?
   ⇨ **If "Yes", continue to complete below.**
   ⇨ **If "No", stop here.**

8. **Medication** *(Give generic name):* _____

9. **Total Dosage:** _____ 10. **Dosage Units** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

11. **Frequency** ☐ *(See Codes below)* ⇨ If "other", Specify: _____ 12. **Mode of Administration** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

13. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨ 14. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

15. **Primary Reason for Use or Change:** _____

16. **Medication** *(Give generic name):* _____

17. **Total Dosage:** _____ 18. **Dosage Units** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

19. **Frequency** ☐ *(See Codes below)* ⇨ If "other", Specify: _____ 20. **Mode of Administration** ☐ *(See Codes below)* ⇨ If "other", Specify: _____

21. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨ 22. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

23. **Primary Reason for Use or Change:** _____

Dosage Units Codes: **(1)** mg, **(2)** mcg or ug, **(3)** ml or cc, **(4)** units, **(5)** g, **(6)** Other (specify)

Frequency Codes: **(1)** Single Dose, **(2)** BID, **(3)** TID, **(4)** QID, **(5)** PRN, **(6)** Q4h, **(7)** Other (specify)

Mode of Administration Codes: **(1)** Intravenous, **(2)** Oral, (3) Intra-muscular, **(4)** Sub-lingual, **(5)** Intra-urethral, **(6)** Patches, **(7)** Other (specify)

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Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

CAM24 – Urology Medication Tracking Form (REVISED 10/13/08)

Two separate medications can be reported on one form. For additional medications, please use an additional CAM24 and enter the page number in field 3.

Since the number of pages required for these forms will vary with the patient, page numbers have been omitted from these headers. Please be sure to fill in the page number along with other header information.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: If SV1, indicate whether or not the participant has taken any urology medications during the last 6 months. If this is not SV1, indicate whether or not the participant has started or stopped any urology medications since the last visit. **If yes, complete fields 8-21.**

Field 8: Enter the generic name of the medication.

Field 9: Enter the total dosage.

Field 10: Enter the dosage units. Refer to the dosage unit codes at the bottom of the form.

Field 11: Enter the frequency of dose. Refer to the frequency codes at the bottom of the form.

Field 12: Enter the mode of administration. Refer to the mode of administration codes at the bottom of the form.

Field 13: Enter the date the medication was started.

Field 14: Enter the date the medication was stopped **OR** check “Ongoing”.

Draft

CAMUS Clinical Trial
Urology Medication Tracking Form (CAM24)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: ☐
4. Visit Number: ☐☐

01=SV1.0	04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

5. Site#: ☐☐☐
6. Staff ID: ☐☐

Do not duplicate medications listed on the Concomitant Medication Form (CAM23). Number page(s) in upper right corner of the form.

Circle the appropriate number

	Yes	No	Don't Know
7. If this is screening visit 1, has the participant taken any urology medications during the last 6 months? If this is not screening visit 1, since the last visit, has the participant started or stopped any urology medications?	1	2	3

⇨ **If "Yes", continue to complete below.**

⇨ **If "No", stop here.**

8. **Medication** *(Give generic name):* _____

9. **Total Dosage:** _____

10. **Dosage Units** ☐ ⇨ If "other", Specify: _____
(See Codes below)

11. **Frequency** ☐ ⇨ If "other", Specify: _____
(See Codes below)

12. **Mode of Administration** ☐ ⇨ If "other", Specify: _____
(See Codes below)

13. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨ 14. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

15. **Medication** *(Give generic name):* _____

16. **Total Dosage:** _____

17. **Dosage Units** ☐ ⇨ If "other", Specify: _____
(See Codes below)

18. **Frequency** ☐ ⇨ If "other", Specify: _____
(See Codes below)

19. **Mode of Administration** ☐ ⇨ If "other", Specify: _____
(See Codes below)

20. **Date Started** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐ **Ongoing:** ☐ *Or* ⇨ 21. **Date Stopped** *(mm/dd/yyyy)* ☐☐/☐☐/☐☐☐☐

Dosage Units Codes: **(1)** mg, **(2)** mcg or ug, **(3)** ml or cc, **(4)** units, **(5)** g, **(6)** Other (specify)

Frequency Codes: **(1)** Single Dose, **(2)** BID, **(3)** TID, **(4)** QID, **(5)** PRN, **(6)** Q4h, **(7)** Other (specify)

Mode of Administration Codes: **(1)** Intravenous, **(2)** Oral, (3) Intra-muscular, **(4)** Sub-lingual, **(5)** Intra-urethral, **(6)** Patches, **(7)** Other (specify)

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October 13, 2008 CAM24 RS

Toll Free Fax: (866) 935-7453
Toll Number: (205) 975-7453

CAM 31 – Vital Signs Form (REVISED 10/10/08)

The old forms for this study ask for the BP to be taken both lying down and standing.

For this study, you only need to take two consecutive measurements five minutes apart, both sitting down

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the 3-digit site number.

Field 4: This field is pre-filled.

Field 5: Enter the visit number. Refer to the table.

Field 6: Enter the initials of the staff person completing the form.

Field 7: Check the appropriate visit type.

The vital signs have to be recorded at the first screening visit or the second visit.

Field 8: Indicate whether or not vital signs were obtained. If yes, complete questions 9-11.

Draft

CAMUS Clinical Trial
Vital Signs Form (CAM31)

Visit Date 1. ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)

2. Participant ID ☐☐☐S☐☐☐

3. Site# ☐☐☐

Page Number 4. 1

Visit Number 5. ☐☐

01=SV1.0 02=SV2.0	04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

Staff ID 6. ☐☐

Visit type
7. ☐ In-Clinic Visit
☐ Telephone Interview

Circle the appropriate number	Yes	No
8. Were vital signs done at this visit? ⇨ **If "No", stop here.** **If "Yes", record below.**	1	2

9. Height: ☐☐ inches (In-Clinic Only)

10. Weight: ☐☐☐ pounds (In-Clinic Only)

11. Seated measurements (reading 1 taken immediately, reading 2 taken 1 minute later):

(a) Blood pressure reading 1 ☐☐☐ (Systolic) / ☐☐☐ (Diastolic) mm Hg

(b) Heart rate reading 1 ☐☐☐ bpm

(c) Time of Day 1 ☐☐☐☐ ☐ AM ☐ PM

(d) Blood pressure reading 2 ☐☐☐ (Systolic) / ☐☐☐ (Diastolic) mm Hg

(e) Heart rate reading 2 ☐☐☐ bpm

CAM41 – PSA Sample Collection (REVISED 10/10/08)

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

A PSA level above 10ng/ml is an exclusionary criterion.

All PSA levels for the study are done at the same laboratory. The blood sample has to be collected and sent to the laboratory as set forth in the section on sample collection.

When the PSA level comes back, it is recorded on this same form.

In the old forms where there is only one decimal place, please just record the first number after the decimal. **There is no need to round up or down**.

Field 7: Indicate whether or not a serum PSA sample was collected. If yes, record the date of collection and complete fields 8-10.

Field 8: Indicate whether or not the serum PSA sample was shipped to central lab.

Field 9: Record the date of shipment.

Field 10: Record the PSA results.

[redacted] F1 Draft

CAMUS Clinical Trial
PSA Sample Collection (CAM41)

1. Visit Date: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0; 24=Week 24, 48=Week 48, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

Circle the appropriate number

Serum PSA:

	Yes	No
7. Was a serum PSA sample collected at this visit?	1	2

⇨ If "Yes", record date of collection. ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)

⇨ If "No", STOP.

	Yes	No
8. *Was a serum PSA sample shipped to central lab?	1	2

9. *If "Yes", record the date of shipment: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)

10. PSA results from Central Lab: ☐☐.☐☐ ng/ml

For screening visit 1, excluded if serum prostate specific antigen level > 10 ng/ml.

**Does not apply to site# 277*

CAM42 – Uroflow Measurement Form (REVISED 10/10/08)

This form records information from the Uroflow tests.

Peak flow rate < 4 ml/sec and voided volume < 125 ml are both exclusionary criteria.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not uroflow measurements were obtained. If yes, complete fields 8-14.

Draft

CAMUS Clinical Trial
Uroflow Measurement Form (CAM42)

Visit Date ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)

Participant ID 2. ☐☐☐S☐☐☐

Page Number 3. 1

Visit Number ☐☐

01=SV1.0 02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

Site# 5. ☐☐☐

Staff ID 6. ☐☐

Circle the appropriate number	Yes	No
7. Were uroflow measurements done at this visit?	1	2

⇨ **If "No", stop here.**
If "Yes", record below.

8. Voiding time: ☐☐☐ sec

9. Flow time: ☐☐☐ sec

10. Time to maximum flow: ☐☐☐ sec

11. Peak flow rate: ☐☐.☐☐ ml/sec

For screening visits 1 and 2: Excluded if peak flow rate is less than 4 ml/sec.

12. Mean flow rate: ☐☐.☐☐ ml/sec

13. Voided volume: ☐☐☐☐ ml

For screening visits: Excluded if voided volume < 125 ml.

14. Post-void residual: ☐☐☐ ml

CAM45 – CBC, Serum Chemistries, Prothrombin Time and EKG Form (REVISED 10/14/08)

The old forms only ask if the values were normal or abnormal.
The old forms have boxes that you place a mark in.

The new forms record actual values for all the laboratory measures.
The new forms have the codes (1, = yes, 2 = no, 3 = don't know) that should be circled.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a complete blood count was obtained. If yes, complete a-e.

Field 8: Record the prothrombin time.

Field 9: Indicate whether or not a serum chemistry panel was obtained. If yes, complete a-i.

Field 10: For baseline, 24, 48 and 72 week visits, indicate whether or not an EKG was performed.

Recording whether an EKG is normal or abnormal with respect to recent MI or active Ischemia should be based on a Final report from a cardiologist.

All attempts should be made to ensure that these reports are received in a timely manner, so that the second screening visit and randomization visits can be scheduled in a timely fashion.

If any values are abnormal, complete the adverse events form (CAM81).

Draft

CAMUS Clinical Trial
CBC, Serum Chemistries, Prothrombin Time and EKG Form (CAM45)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0; 12=Week 12; 24=Week 24; 36=Week 36; 48=Week 48; 60=Week 60; 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

Circle the appropriate number

7. Complete blood count:

	Yes	No
Was a complete blood count done at this visit?	1	2

If "No", skip to question 8. If "Yes", record below.

		Normal	Abnormal	Not Done
(a) Leukocyte count (WBC):	☐☐.☐☐ thou/cmm	1	2	3
(b) Erythrocyte count (RBC):	☐☐.☐☐ mill/cmm	1	2	3
(c) Hemoglobin:	☐☐.☐☐ g/dl	1	2	3
(d) Hematocrit:	☐☐.☐☐ %	1	2	3
(e) Platelet count:	☐☐.☐☐ thou/cmm	1	2	3

If any values are abnormal, complete adverse events form (CAM81).

8. Prothrombin time:

☐☐.☐☐ **Seconds** ☐☐.☐☐ **Upper limit of normal or control value (Seconds)** **INR:** ☐.☐☐

9. Serum chemistries:

	Yes	No
Was a serum chemistry panel done at this visit?	1	2

If "No", stop. If "Yes", record below.

		Normal	Abnormal	Not Done
(a) Sodium:	☐☐☐.☐☐ meq/l	1	2	3
(b) Potassium:	☐☐☐.☐☐ meq/l	1	2	3
(c) Chloride:	☐☐☐.☐☐ meq/l	1	2	3
(d) Bicarbonate:	☐☐.☐☐ meq/l	1	2	3
(e) Glucose:	☐☐☐.☐☐ meq/l	1	2	3
(f) Creatinine	☐☐☐.☐☐ meq/l	1	2	3
(g) ALT (SGPT):	☐☐.☐☐ IU/L	1	2	3
(h) AST (SGOT):	☐☐.☐☐ IU/L	1	2	3
(i) GGT:	☐☐.☐☐ IU/L	1	2	3

8. Complete this section every Baseline, 24, 48 and 72 week visit only.

Electrocardiogram:	1	2	3

If any values are abnormal, complete adverse events form (CAM81).

CAM46 – Urinalysis Form (REVISED 10/10/08)

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a urinalysis was performed. If yes, complete fields 8-9

Field 8: Record the results based on the dipstick test.

Field 9: Record the results based on the microscopic urinalysis.

[redacted]

Draft

CAMUS Clinical Trial
Urinalysis Form (CAM46)

Page Number 3. 1

1. Visit Date ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

2. Participant ID ☐☐☐S☐☐☐

4. Visit Number ☐☐ (01=SV1.0, 72=Week 72)

5. Site# ☐☐☐

6. Staff ID ☐☐

Circle the appropriate number	Yes	No
7. Was an urinalysis done at this visit?	1	2

⇨ **If "Yes", record the results below.**

⇨ **If "No", stop.**

(8) Dipstick

(a) pH: ☐.☐

	0	*trace*	*1+*	*2+*	*3+*	*4+*
(b) Glucose	1	2	3	4	5	6
(c) Blood	1	2	3	4	5	6
(d) Ketones	1	2	3	4	5	6
(e) Protein	1	2	3	4	5	6
(f) Leukocyte esterase	1	2	3	4	5	6

(9) If dipstick is positive (> 0) for blood or leukocyte esterase, send specimen for microscopic urinalysis and code results below.

	none, negative, WNL	*1-5, trace, present, slight, rare*	*6-15, moderate*	*16-30, many, frequent*	*>30, innumerable, TNTC*
(a) WBC	1	2	3	4	5
(b) RBC	1	2	3	4	5
(c) Epithelial cells	1	2	3	4	5
(d) Mucous	1	2	3	4	5
(e) Bacteria	1	2	3	4	5
(f) Casts hyaline	1	2	3	4	5
(g) Casts other	1	2	3	4	5

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October 10, 2008 CAM46 RS

[redacted]

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Toll Number: (205) 975-7453

CAM47 – Serum for Banking Form (REVISED 10/10/08)

If the patient has consented to it, a serum sample from the patient collected at the first visit and the separation visit is to be sent to the NIDDK repository. The samples are being collected and stored for future ancillary studies.

This form is used to identify patients whose sample is collected during SV1.0 and sent to the NIDDK.

If no sample is collected, the reasons for not collecting are also recorded.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not a serum sample was collected.

Field 8: Enter the date of collection if applicable.

Field 9: Indicate the reason specimens were not obtained if applicable.

Field 10: Indicate whether or not the sample was shipped.

Field 11: Enter the date of shipment if applicable.

[redacted] Draft

CAMUS Clinical Trial
Serum for Banking Form (CAM47)

1. Visit Date: ☐☐ / ☐☐ / ☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

Circle the appropriate number

	Yes	No
7. Was a serum sample collected at this visit?	1	2

8. If "Yes", Date of collection: ☐☐ / ☐☐ / ☐☐☐☐ (mm / dd / yyyy)

9. If specimens were not obtained for CAMUS, please indicate reason (Check only one).

☐ (1)Patient refused to give informed consent for CAMUS serum studies (banking).

☐ (2)Patient was not asked to consider CAMUS serum studies (banking).

☐ (3)Other, specify: _____

	Yes	No
10. Was a serum sample shipped to NIDDK repository?	1	2

11. If "Yes", record the date of shipment: ☐☐ / ☐☐ / ☐☐☐☐ (mm / dd / yyyy)

CAM62 – Permanent Discontinuation of CAMUS Study Assessment form (REVISED 10/13/08)

Complete this form only when a participant has gone off protocol treatment and ended follow-up visits.

This form requires the Investigator's signature.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the report (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Enter the date of the participant's last study visit (month, day, and year).

Field 8: Circle the number corresponding to the main reason for termination of follow-up visit.

CAMUS Clinical Trial
Permanent Discontinuation of CAMUS Study Assessment Form
(CAM62)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐

04=Week 4	28=Week 28	52=Week 52
12=Week 12	36=Week 36	60=Week 60
24=Week 24	48=Week 48	72=Week 72

5. Site#: ☐☐☐
6. Staff ID: ☐☐

Complete this form only when a participant has gone off protocol treatment and ended follow-up visits.

7. Date of last study visit: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)

8. Main reason for termination of follow-up visit (circle one):

1 End of Study
2 Participant withdrew consent, refused to participate further
3 Participant lost to follow-up
4 Protocol violation
5 Participant experienced nonfatal medical condition or event
6 Participant experienced adverse events (Complete form CAM81)
7 Participant died (Complete forms CAM81, CAM82, and CAM91)
8 Moved out of any clinic area
9 Other

Brief explanation if (2), (4), (5), (6) or (9) is circled:

_____

_____

_____

_____

_____

Investigator Signature: _____ **Date:** _____

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CAM71 – Jenkins Sleep Dysfunction Scale Form (REVISED 10/10/08)
The CAM71S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6.

The participant completes fields 7-10.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-10: The participant completes these fields.

Draft

CAMUS Clinical Trial
Jenkins Sleep Dysfunction Scale Form (CAM71)

1. Visit Date ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy)
2. Participant ID ☐☐☐S☐☐☐
3. Page Number 1
4. Visit Number ☐☐ (03=Baseline; 24=Week 24, 48=Week 48, 72=Week 72)
5. Site# ☐☐☐
6. Staff ID ☐☐

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number that best describes your condition.*

In the past month, how often did you:

	not at all	*1-3 days*	*4-7 days*	*8-14 days*	*15-21 days*	*22-31 days*
7. Have trouble falling asleep?	0	1	2	3	4	5
8. Wake up several times per night?	0	1	2	3	4	5
9. Have trouble staying asleep (including waking far too early)?	0	1	2	3	4	5
10. Wake up after your usual amount of sleep feeling tired and worn out?	0	1	2	3	4	5

CAM74 – Bladder Function Form (REVISED 10/09/08)
The CAM74S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6 AND field 13.

The participant completes fields 7-12 AND field 14.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-12: The participant completes these fields.

Field 13: The Study Coordinator calculates the ICSmaleIS Score.

Field 14: The participant completes this field.

Draft

CAMUS Clinical Trial
Bladder Function Form (CAM74)

Visit Date: ___/___/____ (mm / dd / yyyy)

Participant ID: 2. ___S___

Page Number: 3. 1

Visit Number: 4. ___ (02=SV2.0; 12=Week 12, 24=Week 24; 36=Week 36, 48=Week 48; 60=Week 60, 72=Week 72)

Site#: 5. ___

Staff ID: 6. ___

This form is completed by the participant.

Instructions: *We would like to find out about your urinary symptoms and we are very grateful that you can help us by filling in this questionnaire. For each question, circle the appropriate number that best describes your condition. Please answer each question, thinking about the symptoms you have experienced in the last month. You will see that some questions ask how often you have a symptom:*

Occasionally = less than one third of the time
Sometimes = between one and two thirds of the time
Most of the time = more than two thirds of the time

In the past month how often:	Never	Occasionally	Sometimes	Most of the time	All of the time
7. Did you have to rush to the toilet to urinate?	0	1	2	3	4
8. Did urine leak before you could get to the toilet?	0	1	2	3	4
9. Did urine leak when you coughed or sneezed?	0	1	2	3	4
10. Did you leak for no obvious reason and without feeling that you wanted to go?	0	1	2	3	4
11. Did you leak urine when you were asleep?	0	1	2	3	4
12. Did you have a slight wetting of your pants a few minutes after you had finished urinating?	0	1	2	3	4

13. *To be completed by the study coordinator: ICSmaleIS Score =* ____ *(Total of items 7-12.)*

Draft

CAMUS Clinical Trial
Bladder Function Form (CAM74)

Participant ID
2. [ ][ ][ ]S[ ][ ][ ]

Page Number
3. 2

Visit Number
4. [ ][ ]

02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

	Very dissatisfied	Moderately dissatisfied	About equally satisfied and dissatisfied	Moderately satisfied	Very satisfied
14. If you had to spend the rest of your life with your urinary or bladder function just the way it is now, how would you feel about that?	1	2	3	4	5

CAM75 – International Prostate Symptom Score (IPSS) (REVISED 10/09/08)

This form is completed by the participant. The header information should be completed by the study coordinator.

The old forms have boxes that you place a mark in.

The new forms record actual values for all the laboratory measures.
The new forms have the codes (1, = yes, 2 = no, 3 = don't know) that should be circled.

Questions 7-13 assess the degree of discomfort BPH is causing the participant. The answers are scaled from 0 to 5, 0 indicating no discomfort and 5 indicating a lot. The AUA score is calculated by adding the scores of the answers to questions 7-13.

Questions 15 & 16 should also be completed but not included in the score.

The completion of the TPSS form completes all the requirements for the SV1.0.

Please fax completed forms to the DCC. Forms should be faxed in within 3 days of the SV1.0.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-13: These fields are completed by the participant.

Field 14: The study coordinator enters the AUASS.

Fields 15-16: These fields are completed by the participant.

[redacted] Draft

CAMUS Clinical Trial
International Prostate Symptom Score (IPSS) For (CAM75)
(AUA Symptom Score & IPSS Quality of Life Questions)

1. Visit Date: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (01=SV1.0, 02=SV2.0, 12=Week 12, 24=Week 24, 36=Week 36, 48=Week 48, 60=Week 60, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number that best describes your condition.*

	not at all	*less than 1 time in 5*	*less than half the time*	*about half the time*	*more than half the time*	*almost always*
7. Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
8. Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5
9. Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
10. Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5
11. Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5
12. Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5
	None	*1 time*	*2 times*	*3 times*	*4 times*	*5 or more times*
13. Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	0	1	2	3	4	5

14. *To be completed by the study coordinator:* *AUASS =* ☐☐☐☐ *(Total of items 7-13.)*

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[redacted]

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CAMUS Clinical Trial
International Prostate Symptom Score (IPSS) For (CAM75)
(AUA Symptom Score & IPSS Quality of Life Questions)

Participant ID
2. [ ][ ][ ][S][ ][ ][ ]

Page Number
3. 2

Visit Number
4. [ ][ ]

01=SV1.0 02=SV2.0	12=Week 12 24=Week 24	36=Week 36 48=Week 48	60=Week 60 72=Week 72

	Delighted	*Pleased*	*Mostly satisfied*	*Mixed-about equally satisfied and dissatisfied*	*Mostly dissatisfied*	*Unhappy*	*Terrible*
15. If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	1	2	3	4	5	6	7

	Not at all	*Less than 1 time in 5*	*Less than half the time*	*About half the time*	*More than half the time*	*Almost always*
16. Over the past month, how often when you felt the urge to urinate, did you leak urine before you could get to the toilet?	1	2	3	4	5	6

CAM77 – Subjective Global Assessment Form (REVISED 10/10/08)
The CAM77S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6.

The participant completes fields 7-10.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7-10: The participant completes these fields.

Draft

CAMUS Clinical Trial
Subjective Global Assessment Form (CAM77)

1. Visit Date: ☐☐/ ☐☐/ ☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: 1
4. Visit Number: ☐☐ (24=Week 24, 48=Week 48, 72=Week 72)
5. Site#: ☐☐☐
6. Staff ID: ☐☐

This form is completed by the participant.

Instructions: *For each question, circle the appropriate number that best describes your urinary symptoms.*

	Much Better	*Somewhat better*	*A little better*	*About the same*	*A little worse*	*Somewhat worse*	*Much worse*
7. Compared to the beginning of the study, how are your urinary symptoms now?	1	2	3	4	5	6	7
8. Compared to the beginning of the study, how are your urinary incontinence symptoms now?	1	2	3	4	5	6	7

	Very satisfied	*Somewhat satisfied*	*Neither satisfied nor dissatisfied*	*Somewhat dissatisfied*	*Very dissatisfied*
9. How satisfied or dissatisfied are you with any urinary symptoms you have now?	1	2	3	4	5
10. How satisfied or dissatisfied are you with any urinary incontinence symptoms you have now?	1	2	3	4	5

CAM79 – Participant Treatment Perception Form (REVISED 10/10/08)
The CAM79S is the Spanish version of the form. If needed the participant's should be provided with the services of a translator to help fill in these forms.

The Study Coordinator completes fields 1-6.

The participant completes fields 7.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: This field is pre-filled.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Fields 7: The participant completes this field.

Draft

CAMUS Clinical Trial
Participant Treatment Perception Form (CAM79)

1. Visit Date ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)
2. Participant ID ☐☐☐S☐☐☐
3. Page Number 1
4. Visit Number ☐☐ (24=Week 24, 48=Week 48, 72=Week 72)
5. Site# ☐☐☐
6. Staff ID ☐☐

Question 7 is to be completed at every 24, 48, and 72 weeks.

Circle the appropriate number

	I am not sure which treatement I am getting	*I think I am getting the placebo pills (no active treatement)*	*I think I am getting the Saw palmetto plant extract*	*I am not taking any CAMUS pills right now*
7. What is your best guess about what treatment you are getting as part of the CAMUS study?	1	2	3	4

CAM81 – Adverse Event Form (REVISED 10/13/08)

An adverse event is an unexpected medical problem that happens during treatment with a drug or other therapy. Adverse events do not have to be caused by the drug or therapy, and they may be mild, moderate, or severe. **All adverse events, regardless of severity, and whether or not ascribed to the study drug administration, should be recorded on CAM81.** All grade 3, 4 and 5 adverse events will be reviewed by the Clinical Review Committee.

Please refer to the document entitled 'SAE reporting Guidelines' provided by the American College of Surgeons – Oncology Group in the Appendix, for more details on the grading SAEs, attributing causes to SAEs and reporting of SAEs.

Header information: The information in the header is critical to ensure data quality. Please make sure you fill this in clearly and legibly.

Field 1: Enter the date of the visit (month, day, and year).

Field 2: Enter the participant ID.

Field 3: Enter the page number.

Field 4: Enter the visit number. Refer to the table.

Field 5: Enter the 3-digit site number

Field 6: Enter the initials of the staff person completing the form.

Field 7: Indicate whether or not the participant has experienced an adverse event since the last visit.

If yes, complete fields 8-18. (An additional event can be reported in fields 9-29.) Please refer to the table at the bottom of the page for applicable codes.

Draft

CAMUS Clinical Trial
Adverse Event Form (CAM81)

1. Visit Date: ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)
2. Participant ID: ☐☐☐S☐☐☐
3. Page Number: ☐
4. Visit Number: ☐☐

04=Week 4 12=Week 12 24=Week 24	28=Week 28 36=Week 36 48=Week 48	52=Week 52 60=Week 60 72=Week 72

5. Site# ☐☐☐
6. Staff ID ☐☐

Circle the appropriate number

	Yes	No	
7. Has the participant experienced an adverse event since the last visit ?	1	2	⇨ If "Yes", record below. ⇨ If "No", stop here.

8. **MEDDRA Code:** ☐☐☐☐☐☐☐☐
9. **Description:** _____

10. **Date of Onset:** ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy) **Continuing** ☐ **OR** 11. **Date Resolved:** ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)
12. **Serious?** ☐ No ☐ Yes ⇨ *Complete SAE Form (CAM82)* 13. **Severity** *(See Codes):* ☐
14. **Relationship to Study** *(See Codes):* ☐ 15. **Outcome** *(See Codes):* ☐ 16. **Anticipated?** ☐ No ☐ Yes
17. **Action Taken** 1 2 3 4 5 6 *(See Codes & circle all that apply):* 18. **Action Taken Regarding Study Drug** *(See Codes):* ☐

19. **MEDDRA Code:** ☐☐☐☐☐☐☐☐
20. **Description:** _____

21. **Date of Onset:** ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy) **Continuing** ☐ **OR** 22. **Date Resolved:** ☐☐/☐☐/☐☐☐☐ (mm / dd / yyyy)
23. **Serious?** ☐ No ☐ Yes ⇨ *Complete SAE Form (CAM82)* 24. **Severity** *(See Codes):* ☐
25. **Relationship to Study** *(See Codes):* ☐ 26. **Outcome** *(See Codes):* ☐ 27. **Anticipated?** ☐ No ☐ Yes
28. **Action Taken** 1 2 3 4 5 6 *(See Codes & circle all that apply):* 29. **Action Taken Regarding Study Drug** *(See Codes):* ☐

Relationship to Study Codes: (1) Unrelated, (2) Unlikely, (3) Possible, (4) Probable, (5) Definite

Severity: (1) Mild, (2) Moderate, (3) Severe, (4) Life Threatening, (5) Death

Outcome Codes: (1) Complete recovery w/o residual effect, (2) Recovered w/ residual effect, (3) Recovered w/ persistent effect, (4) Not yet recovered, (5) Died

Action Taken Codes: (1) Self or OTC treatment, (2) Office, clinic, ER, or out-pt visit, (3) In-pt visit or hosp admit, (4) Rx, (5) Procedure performed, (6) None

Action Taken Regarding Study Drug Codes: (0) Not applicable, (1) None, (2) Reduced, (3) Interrupted, (4) Discontinued

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