

MIST2 Form SCR1, Screening Visit 1 (version June 1, 2007)

Participant ID (3 digits)

RELEASEID

Visit ID = S01

VISITID

Demographics and Social Characteristics

1. Age in years *Excluded if < 50 years old.*
2. Race/ethnicity ₁ White Non-Hispanic ₂ Other ₃ Unknown/not reported
3. Are you married or in a long-term committed relationship? ₀ No ₁ Yes

AGE

RACEETH

SIMARRIE

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).

- | | No | Yes | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|---------------------------------------|----------|
| 4. Congenital disease. <i>Probe with:</i> Were you born with a birth defect or an unusual condition such as malformation of the limbs, head, skin, or internal organs? | <input type="checkbox"/> ₀ | <input type="checkbox"/> ₁ | S1CONGEN |
| 5. Pulmonary disease. <i>Probe with:</i> Do you have chronic obstructive pulmonary disorder (COPD), asthma, chronic bronchitis, pneumonia, or pleural effusion? | <input type="checkbox"/> ₀ | <input type="checkbox"/> ₁ | S1PULMON |
| 6. Cardiovascular disease. <i>Probe with:</i> Do you have angina, myocardial infarction, congestive heart failure, hypertension, arrhythmia, peripheral vascular disease, congenital heart disease, syncope (NOS), valvular heart disease, bypass, or coronary artery disease? <i>Probe for dates as needed for exclusion criteria purposes.</i> | <input type="checkbox"/> ₀ | <input type="checkbox"/> ₁ | S1CARD |
| <i>Excluded if episode of unstable angina pectoris, myocardial infarction, transient ischemic attack, or cerebrovascular accident within the past 6 months.</i> | | | |
| 7. Renal disease. <i>Probe with:</i> Do you have nephrolithiasis, stones, or glomerulo nephritis? | <input type="checkbox"/> ₀ | <input type="checkbox"/> ₁ | S1NEPHRO |
| 8. Rheumatologic/collagen disease. <i>Probe with:</i> Do you have rheumatoid arthritis or lupus? | <input type="checkbox"/> ₀ | <input type="checkbox"/> ₁ | S1RHEUMA |
| 9. Diabetes mellitus. <i>Probe with:</i> Do you have non-insulin dependent or insulin-dependent diabetes mellitus? | <input type="checkbox"/> ₀ | <input type="checkbox"/> ₁ | S1DIABET |
| 10. Endocrine disorder. <i>Probe with:</i> Do you have a pituitary, thyroid, or adrenal disorder, or low testosterone? | <input type="checkbox"/> ₀ | <input type="checkbox"/> ₁ | S1PITUIT |
| 11. Hepatic disease. <i>Probe with:</i> Do you have hepatitis or cirrhosis? | <input type="checkbox"/> ₀ | <input type="checkbox"/> ₁ | S1HEPATI |
| 12. Gastrointestinal disease. <i>Probe with:</i> Do you have peptic ulcer disease, ulcer disease, GERD, GI bleeding, cholelithiasis, cholecystitis, hemorrhoids, constipation, diarrhea, polyps, inflammatory bowel disease, diverticulitis, colitis, Crohn's, or pancreatitis? | <input type="checkbox"/> ₀ | <input type="checkbox"/> ₁ | S1GASTRO |

13. Dermatological disease. *Probe with:* Do you have psoriasis, rosacea, rash, or eczema? ₀ ₁ SIDERMAT
14. Neurological disease. *Probe with:* Do you have seizures, multiple sclerosis, Parkinson's, stroke, numbness, tingling, or muscle weakness? ₀ ₁ SINEUROL
Excluded if known primary neurologic conditions such as multiple sclerosis, myasthenia gravis or Parkinson's disease, or other neurological diseases known to affect bladder function).
15. Neoplastic disease. *Probe with:* Do you have any cancer or carcinoma? ... ₀ ₁ SINEOPLA
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).
16. Anemia ₀ ₁ SIANEMIA
17. Hematologic disease other than anemia. *Probe with:* Do you have sickle cell, leukemia, or a bleeding disorder? ₀ ₁ SIHEMATO
Excluded if bleeding disorder that makes botulinum toxin injection impossible, Eaton-Lambert syndrome, hemophilia, hereditary clotting factors deficiency or bleeding disorder.
18. History of urinary tract infections. *Probe with:* Do you have any of the following urinary conditions: burning, frequency, urgency, hematuria, or bladder spasm? ₀ ₁ SIURINAR
Excluded if
 - *active urinary tract infection as documented by positive culture OR*
 - *two documented UTIs of any type in the past year (UTI defined as > 100,000 colonies per ml urine from midstream clean catch or catheterized specimen).*
19. History of urinary retention. *If yes, check for timing and causes.* ₀ ₁ SIURETEN
20. Prior history of gross or microscopic hematuria. ₀ ₁ SIHEMATU
21. Prior biopsy of prostate..... ₀ ₁ SIBIOP
Excluded if biopsy of the prostate within the past 6 weeks.
22. Vasectomy ₀ ₁ SIVSCT
23. Penile prosthesis ₀ ₁ SIPROSTH
Excluded if penile prosthesis.
24. Artificial urinary sphincter ₀ ₁ SISPHINC
Excluded if artificial urinary sphincter or any implant, metallic or nonmetallic, within 1.5 inches of the prostatic urethra.
25. Impotence. *Probe with:* Do you have any difficulty with erectile function?.... ₀ ₁ SIIMPOTE

26. Overactive bladder. *Excluded if overactive bladder without bladder outlet obstruction.* ₀ ₁ S1OVBLAD
27. Other genitourinary disease. *Probe with: Do you have incontinence?* ₀ ₁ S1GENIT
- Excluded if*
- *history or current evidence of pelvic radiation or surgery, urethral stricture, or bladder neck obstruction OR*
 - *current diagnosis of acute or chronic prostatitis OR*
 - *bacterial or acute prostatitis within the past year documented by positive culture OR*
 - *daily use of a pad or device for incontinence required*
28. Infectious diseases. *Probe with: Do you have any infectious diseases such as HIV, herpes, or tuberculosis?.....* ₀ ₁ S1INFECT
29. Any serious medical condition likely to impede successful completion of the study, such as certain mental thought disorders, hypersensitivity to botulinum toxin, syncope, uncontrolled diabetes. *Excluded if yes to any.* ₀ ₁ S1SMCOND
30. History of bladder calculi ₀ ₁ S1BLADDE
- Excluded if history of bladder calculi.*

Family History (blood relations only)

31. Has anyone in your family been told by a physician that he has BPH?
- ₀ No / unknown ₁ Yes ⇒ check all that apply
- ₁ Father S1FABPH
 - ₁ Maternal grandfather S1FABPH1
 - ₁ Maternal uncle(s) S1FABPH2
 - ₁ Brother(s) S1FABPH3
 - ₁ Paternal grandfather S1FABPH4
 - ₁ Paternal uncle(s) S1FABPH5
32. Has anyone in your family been told by a physician that he has prostate cancer?
- ₀ No / unknown ₁ Yes ⇒ check all that apply
- ₁ Father S1FACAN
 - ₁ Maternal grandfather S1FACAN1
 - ₁ Maternal uncle(s) S1FACAN2
 - ₁ Brother(s) S1FACAN3
 - ₁ Paternal grandfather S1FACAN4
 - ₁ Paternal uncle(s) S1FACAN5

BPH Symptoms

33. For how long have you had symptoms of BPH? . years

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

35. Have you seen a physician within the past 5 years about BPH symptoms? ₀ No ₁ Yes

If yes, what was recommended? Check all that apply.

a. ₁ Watchful waiting

b. ₁ TURP or other surgical procedure

c. ₁ Prescription medication

If yes, what was done? Check all that apply.

d. ₁ Watchful waiting

e. ₁ TURP or other surgical procedure

Excluded if any prior surgical intervention for BPH.

f. ₁ Prescription medication

Uroflow Measurements

36. Voiding time sec
37. Flow time sec
38. Time to maximum flow sec
39. Maximum flow rate . ml/sec *Excluded if ≥ 15 ml/sec*
40. Mean flow rate . ml/sec
41. Voided volume ml *Excluded if voided volume < 125 ml.*
42. Post-void residual ml *Excluded if post-void residual > 350 ml.*

Lab Results

43. Serum PSA (taken within the previous 6 months) . ng/ml
Excluded if serum prostate specific antigen level > 8 ng/ml. For those with a PSA between 4-8 ng/ml, the PSA elevation must be considered to be from a benign cause in the opinion of the PI. This decision can be based on PSA velocity, previous TRUS biopsy, percent free PSA, or other clinical estimations in keeping with sound urologic care.
44. Complete blood count (taken within last month if available, otherwise obtain specimens)
- (a) Leukocyte count (WBC) . $10^3/\text{ul}$
- (b) Erythrocyte count (RBC) . $10^6/\text{ul}$
- (c) Hemoglobin . g/dL
- (d) Hematocrit . %
- (e) Platelet count $10^3/\text{ul}$

45. Serum chemistries (taken within last month if available, otherwise obtain specimens)

(a) Sodium mmol/L

S1SODIUM

(b) Potassium . mmol/L

S1POTASS

(c) Chloride mmol/L

S1CHLORI

(d) Carbon dioxide (CO₂) mmol/L

S1CO2

(e) Glucose mg/dL

S1BLGLUC

(f) Creatinine . mg/dL

S1CREATI

Excluded if clinically significant renal or hepatic impairment as determined by abnormal creatinine level (i.e., creatinine > 2.0 mg/dL).

(g) BUN mg/dL

S1BUN

(h) AST (SGOT) U/L

S1AST

Excluded if clinically significant renal or hepatic impairment as determined by abnormal AST level (i.e., AST > 1.5 times the upper limit of institutional norms).

46. Urinalysis (taken within last month if available, otherwise obtain specimens)

(a) Dipstick

| | | | | | | | | |
|----------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|-----------------------------------|---------------------------------------|
| • pH | <input type="text"/> | <input type="text"/> | | | | | <input type="text" value="S1PH"/> | |
| | | <i>0</i> | <i>trace</i> | <i>1+</i> | <i>2+</i> | <i>3+</i> | <i>4+</i> | |
| • Glucose | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text" value="SIURGLUC"/> |
| • Blood | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text" value="S1BLOOD"/> |
| • Ketones | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text" value="SIKETONE"/> |
| • Protein | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text" value="S1PROTEI"/> |
| • Leukocyte esterase | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text" value="S1LEUKOC"/> |

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

| | | | | | | | |
|--------------------|--------------------------|------------------------------------|-----------------------------------------------------------|---------------------------|--------------------------------------|-------------------------------------------|---------------------------------------|
| | | <i>none, negative, WNL</i> | <i>1-5, trace, present, slight, rare, occ</i> | <i>6-15, moderate</i> | <i>16-30, many, frequent</i> | <i>> 30, innumerable, TNTC</i> | |
| • WBC | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text" value="SIURWBC"/> |
| • RBC | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text" value="SIURRBC"/> |
| • Epithelial cells | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text" value="S1EPITHE"/> |
| • Mucous | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text" value="SIMUCOUS"/> |
| • Bacteria | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text" value="S1BACTER"/> |
| • Casts hyaline | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text" value="S1CASTSH"/> |
| • Casts other | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text" value="S1CASTSC"/> |