8.3. SPECIFIC INSTRUCTIONS FOR THE COMPLETION OF DATA FORMS

This section provides specific instructions for the correct completion of data forms. The forms are listed in alphabetical order.

For each data form, the following information is provided: the purpose of the form, who completes the form, when the form should be completed, and specific instructions. Appendix E also contains a list of all data forms, when they should be completed, and who should complete them.

If you are unable to find specific information that you need to complete the form, please contact the ICDB Data Manager.

8.3.1 Background Information (BACK)

Purpose: To collect demographic and other background information.

Who: Completed by the patient and reviewed by the RC.

When: Screening Phase.

Instructions:

Q4: If the patient has more than one address, use the zip code of the address where she/he receives her/his mail.

Q5: The races listed on this form are defined as follows:

Aleut, Eskimo or American Indian: A person having origins in any of the original peoples of North America, who maintains cultural identification through tribal affiliation or community recognition.

*Asian or Pacific Islande*r: A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands, and Samoa.

Black: A person having origins in any of the black racial groups of Africa.

White: A person having origins in any of the peoples of Europe or the Middle East.

Q6: *Latino/Hispanic:* A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture of origin, regardless of race.

Q7: The religions listed on this form are defined as follows:

Protestant: The Protestant religions include denominations such as Baptist, Episcopalian, Lutheran, Methodist United Church of Christ, etc.

Q8: This question should indicate the patient's most recent marital status. For example, if the patient is widowed and remarried, mark married.

8.3.2 Background Information (BACKF)

Purpose: To collect updated demographic and other background information.

Who: Completed by the patient and reviewed by the RC.

When: Extensive Clinic Visits.

Instructions:

Q1: If the patient has more than one address, use the zip code of the address where she/he receives her/his mail.

Q3: This question should indicate the patient's most recent marital status. For example, if the patient is widowed and remarried, mark married.

8.3.3 Concomitant Medications (CMED)

Purpose: To collect information regarding medications that a patient is currently taking for reasons *other than her/his urinary symptoms.* This includes both prescription and over-thecounter drugs.

Who: Administered to the patient by the RC.

When: Screening Phase and all follow-up visits.

Instructions:

This form consists of two sections. The first section, "Prior medications stopped since last visit or contact", should be used to record any medications that the patient stopped taking since her/his last ICDB study visit. The second section, "New medications started since last visit or contact", should be used to record any medications that the patient started taking since her/his last ICDB study visit.

Prior medications stopped since last visit or contact: First, indicate the study visit. If this is the first screening visit, check the "none" box and proceed to the "New medications started

since last visit or contact" section. For any other visit type, follow the instructions below.
Review the CMED forms from the patient's previous visits. Ask the patient if she/he has stopped any medications since her/his last visit. If she/he has not stopped any medications since the last visit, check the "none" box and proceed to the "New medications started since last visit or contact" section. If she/he has stopped any medications since the last visit, record these changes in the table.
Instructions for completing the table:
Drug Name: Record the name of the drug exactly as it appeared on the original CMED form where it was recorded as a new medication.
Start Date: Obtain the start date from the original CMED form where the drug was recorded as a new medication.
Stop Date: Ask when the patient stopped taking the drug and record only the month and year of the stop date.
Reason: Record the reason exactly as it appeared on the original CMED form where the drug was recorded as a new medication.
New medications started since last visit or contact: First, indicate the study visit. If this is the first screening visit, record all current concomitant medications in the table or check the "none" box if the patient is not currently taking any concomitant medications. For any other visit type, follow the instructions below.
Review the CMED forms from the patient's previous visits. Ask the patient if she/he has started any new medications since her/his last visit. If she/he has not started any new medications since the last visit, check the "none" box and stop. If she/he has started any new medications since the last visit, record these changes in the table.
Instructions for completing the table:

Drug Name: Record the name of the drug exactly as it appears on the label provided by the patient or as reported by the patient. Verify the accuracy of the drug name, including spelling, with a drug handbook (i.e., *Physician's Desk Reference*).
Start Date: Ask when the patient started taking the drug and record only the month and year of the start date. If the patient does not know the month, record only the year.
Stop Date: If the patient is no longer taking the drug, ask when the patient stopped taking the drug and record only the month and year of the stop date. If the patient is still taking the drug, do not record a stop date and check the "continuing" box.
Reason: Ask the patient why she/he is/was taking this medication and record a brief explanation.

8.3.4 Cystoscopy (CYST)

Purpose: To collect information obtained during the cystoscopy procedure.
Who: Completed by the physician performing the cystoscopy procedure and reviewed by the RC.
When: Any study visit, when clinically indicated.
Instructions:
Q9-Q10, Q15-Q19: The locations of all Hunner's patches, scars, localized glomerulations, and biopsies should be indicated on the bladder map on page 4.
Q12-Q16: These questions should be completed only if a hydrodistention is performed.
Q17-Q19: These questions should be completed only if a biopsy is performed.
The pathology report must be submitted for any screening or follow-up visit packet when a biopsy is performed. Any patient identifying information (i.e., name or hospital ID number) must be removed or covered. The report must contain the red ink laboratory report stamp in the upper or lower right hand corner of the front of the first page. This stamp must indicate the patient ID number, the date that the specimen was *collected*, and the form code "PATH".

8.3.5 Deferral Checklist #1 (DEF1)

Purpose: To assess the patient's eligibility for the study according to a subset of the study deferral criteria.

Who: Administered to the patient by the RC.
When: Screening Phase.
Instructions:
Q1: This refers to positive cultures for bacterial cystitis only. Self-diagnoses or diagnoses by a physician without a culture do not apply.
Q3: This question, for men only, refers to positive cultures for bacterial prostatitis only. Selfdiagnoses or diagnoses by a physician without a culture does not apply.
Q4: If the patient has never heard of the procedure and does not know if she/he has had one, check "unknown".
Eligibility Question: If the patient is deferred, refer to Section 5.4: *Patient Eligibility* for the length of the deferral period. Record the approximate date that the patient will be eligible for the study.

8.3.6 Deferral Checklist #2 (DEF2)

Purpose: To assess the patient's eligibility for the study according to a subset of the study deferral criteria.
Who: Completed by the RC.
When: Screening Phase, after the physical exam and all clinically indicated tests have been performed.
General Instructions:
The visit date on this form should correspond to the date of the last physical exam or clinically indicated test required to complete the form.
Q2: This question cannot be completed until after the urine culture result is known.

8. Data and Administrative Forms Procedures June 14, 1995

8_12 /data/icdb/projmgt/document/mop/chap8/chap8.wp6
The urine culture report must be submitted with the packet of screening phase data forms. Any patient identifying information (i.e., name or hospital ID number) must be removed or covered. The report must contain the red ink laboratory report stamp in the upper or lower right hand corner of the front of the first page. This stamp must indicate the patient ID number, the date that the specimen was *collected*, and the form code "UCULT".
Eligibility Question: If the patient is deferred, refer to Section 5.4: *Patient Eligibility* for the length of the deferral period. Record the approximate date that the patient will be eligible for the study.

8.3.7 Dietary Habits (DIET)

Purpose: To collect information regarding the effect of certain foods on a patient's urinary symptoms.
Who: Completed by the patient and reviewed by the RC.
When: Screening Phase, Brief Clinic Visits, and Extensive Clinic Visits.
Instructions:
The patient should indicate how each food affects her/his urinary symptoms, *if* they eat the food. If the patient marks more than one response for a question, ask the patient to choose the *one* response that *best* answers the question.

8.3.8 Exclusion Checklist #1 (EXCL1)

Purpose: To assess the patient's eligibility for the study according to a subset of the study exclusion criteria.
Who: Administered to the patient by the RC.
When: Screening Phase.
Instructions:
Q5: If the patient has never heard of the procedure and does not know if she/he has had one, check "unknown".

8.3.9 Exclusion Checklist #2 (EXCL2)

8. Data and Administrative Forms Procedures June 14, 1995

8_13 /data/icdb/projmgt/document/mop/chap8/chap8.wp6
Purpose: To assess the patient's eligibility for the study according to a subset of the study exclusion criteria.
Who: Completed by the RC.
When: Screening Phase, after the physical exam and all clinically indicated tests have been

performed.
Instructions:
The visit date on this form should correspond to the date of the last physical exam or clinically indicated test required to complete the form.
Q6: This question cannot be completed until after the CMG has been performed.
8.3.10 Exclusion Checklist #3 (EXCL3)
Purpose: To assess the patient's eligibility for the study according to a subset of the study exclusion criteria.
Who: Completed by the RC.
When: Screening Phase, *if* a cystoscopy, hydrodistention, and biopsy is performed.
Instructions:
The visit date on this form should correspond to the date that the biopsy specimen was collected.
Q1: This question cannot be completed until after the pathology report is completed.
8.3.11 Family History (FHX)
Purpose: To collect information regarding the patient's family medical history.
Who: Administered to the patient by the RC.
When: Screening Phase.
Instructions:

Blood relatives also include half-brothers and half-sisters. Non-blood related family members, including step- and adopted children and siblings, should not be included in the patient's responses.
8.3.12 Hematology (HEM)
Purpose: To collect information obtained from the hematology test.
Who: Completed by the RC.
When: Screening Phase.
Instructions:
The visit date on this form should correspond to the date that the blood specimen was collected. Hematology results should be transcribed from the laboratory report to the data form. If the "units" from the laboratory report are not the same as the "units" listed on the HEM form, then the RC should convert the values to the units requested on the HEM form. If necessary the RC should contact the laboratory for assistance. Make a note on the lab report that the values have been converted to those recorded on the HEM form.
The hematology report must be submitted with the packet of screening phase data forms. Any patient identifying information (i.e., name or hospital ID number) must be removed or covered. The report must contain the red ink laboratory report stamp in the upper or lower right hand corner of the front of the first page. This stamp must indicate the patient ID number, the date that the specimen was *collected*, and the form code "HMRPT".
8.3.13 Inclusion Checklist (INCL)
Purpose: To assess the patient's eligibility for the study according to the study inclusion criteria.
Who: Administered to the patient by the RC.
When: Screening Phase.
Instructions:

Q1: The patient *must* sign the Informed Consent before the screening process can continue. Do not continue with the rest of the form unless the patient has signed the Informed Consent.
Q2: Do not continue with the rest of the form if the patient is not 18 years of age or older.
Q5-Q8: These questions cannot be completed until the Pain and Urgency Scales (PURG) form is completed and reviewed.
Eligibility Question: If the patient is not eligible ("on-hold"), record the approximate date that the patient will be eligible for the study.
8.3.14 Medical Events and Patient Treatment Evaluation (MED)
Purpose: To collect the patient's assessment of her/his overall health and treatment effectiveness; to collect information regarding medical events and treatment effectiveness since the

patient's last study visit or contact.
Who: Administered to the patient by the RC.
When: All follow-up contacts.
Instructions:
Q7: If the patient has had a period within the last 12 months, then check "no"; otherwise, check "yes".
Q9: If the patient does not know the exact date of her last menstrual period, record the month and year.
8.3.15 Patient Medical History (MEDHX)
Purpose: To collect information regarding the patient's medical history.
Who: Administered to the patient by the RC.
When: Screening Phase and Extensive Clinic Visits.
Instructions:

Q1-Q5: Do not complete these questions for male patients.
Q6-Q35: These questions should be answered based only on a physician's diagnosis.
Pap Smear Recommendation: If the patient's last pap smear was abnormal or more than one year ago, you *must* recommend that the patient see her gynecologist for another pap smear.
8.3.16 Physical Exam (PHS)
Purpose: To collect information obtained during the patient's physical examination.
Who: Completed by the physician performing the physical examination and reviewed by the RC.
When: Screening Phase. This form should also be completed during Brief Clinic Visits and Extensive Clinic Visits, when a physical examination is clinically indicated.
Instructions:
Q13-Q16: These questions should be completed only if a neurologic exam is indicated.
8.3.17 Physician's Evaluation and Treatment Plan (PHYTRT)
Purpose: To collect the physician's assessment regarding the patient's overall health and treatment effectiveness; to collect information regarding treatments that a patient is currently using for her/his urinary symptoms.
Who: Completed by the physician performing the evaluation and reviewed by the RC.
When: Screening Phase and all follow-up visits.
Instructions:
The first page of this form collects the overall health assessment, treatment effectiveness and whether or not a cystoscopy will be performed within this visit window.
Q3: This question should be marked "yes" if a cystoscopy has already been performed during this visit window or will be performed during this visit time window. For more details regarding the handling of cystoscopies between follow-up visits, see Section 6.3.4: *Cystoscopy During Follow-Up Visits*.

The last two pages of this form consist of two sections. The first section, "Prior treatments stopped since last visit or contact", should be used to record any treatments that the patient stopped taking since her/his last ICDB study visit. The second section, "New treatments started since last visit or contact", should be used to record any treatments that the patient started taking since her/his last ICDB study visit.
Prior treatments stopped since last visit or contact: First, indicate the study visit. If this is the first screening visit, check the "none" box and proceed to the "New treatments started since last visit or contact" section. For any other visit type, follow the instructions below.
Review the PHYTRT forms from the patient's previous visits. Ask the patient and review the patient's medical chart to determine if she/he has stopped any treatments since her/his last visit. If she/he has not stopped any treatments since the last visit, check the "none" box and proceed to the "New treatments started since last visit or contact" section. If she/he has stopped any treatments since the last visit, record these changes in the table.
Instructions for completing the table:

Treatment: Record the name of the treatment exactly as it appeared on the original PHYTRT form where it was recorded as a new treatment.
Start Date: Obtain the start date from the original PHYTRT form where the treatment was recorded as a new treatment.
Stop Date: Ask when the patient stopped using the treatment and record only the month and year of the stop date.
New treatments started since last visit or contact: First, indicate the study visit. If this is the first screening visit, record all current treatments in the table or check the "none" box if the patient is not currently using any treatments for her/his urinary symptoms. For any other visit type, follow the instructions below.
Review the PHYTRT forms from the patient's previous visits. Ask the patient and review the patient's medical chart to determine if she/he has started any new treatments since her/his last visit. If she/he has not started any new treatments since the last visit, check the "none" box and stop. If she/he has started any new treatments since the last visit, record these changes in the table.
Instructions for completing the table:

Treatment: Record the name of the treatment exactly as it appears on the label provided by the patient or as reported by the patient. Verify the accuracy of all drug names, including spelling, with a drug handbook (i.e., *Physician's Desk Reference*).
Start Date: Determine when the patient started taking the treatment and record only the month and year of the start date. Record only the year if the month is not known.
Stop Date: If the patient is no longer using the treatment, determine and record only the month and year of the stop date. If the patient is still using the treatment, do not record a stop date and check the "continuing" box.
If a treatment is started and stopped on the same day, i.e., a cystoscopy with hydrodistention, then record the start date and stop date as the date of treatment.

8.3.18 Pregnancy History (PREG)

Purpose: To collect information regarding the patient's pregnancy history.
Who: Administered to the patient by the RC.
When: Screening Phase and Extensive Clinic Visits.
Instructions:
Q1: If the patient has had a hysterectomy and had both ovaries removed, then check "yes".
If the patient has had a hysterectomy and still has at least part of one ovary and has experienced menopausal symptoms such as hot flashes, vaginal dryness, and/or discomfort when engaging in sexual relations, then check "yes". If the patient has had a hysterectomy and still has at least part of one ovary and has not experienced any menopausal symptoms, then check "no".
If the patient has not had a hysterectomy and has experienced **any** menopausal symptoms, then check "yes"; otherwise check "no". If the patient has not experienced any symptoms, but has had very irregular periods, with the last period within the last 12 months, then check "no". If her last period was greater than 12 months previously, check "yes".
Q2: If the patient has been pregnant at least one time, complete *all* rows in the "Number of Each" column, using zeroes where applicable. Complete the due date only if the patient is currently pregnant.
Q3-Q8: Complete these questions *only* if the patient has been pregnant at least one time.

Q7-Q8: Complete these questions *only* if any of the pregnancies resulted in live births or stillbirths.

8.3.19 Prior Diagnoses and Treatments (PRIOR)

Purpose: To collect information regarding prior diagnostic tests and treatments for the patient's urinary symptoms.
Who: Administered to the patient by the RC.
When: Screening Phase.
Instructions:

Q2-Q10: If the patient had a particular diagnostic test more than once, record the result of the most recent test.
Q13-Q18, Q20-Q26, Q28-45, Q47-51: If the patient has used multiple episodes of a particular treatment, record the effectiveness of the most recent episode.

8.3.20 Pain and Urgency Scales (PURG)

Purpose: To measure the patient's pain and urgency.
Who: Completed by the patient and reviewed by the RC or administered to the patient by the RC.
When: Screening Phase and all follow-up visits.
Instructions:
One number should be circled on each scale. If the patient responds using a range of numbers, ask her/him to clarify the answer by providing *one* number that best describes her/his pain or urgency.

8.3.21 Quality of Life (QUL)

Purpose: To collect information regarding the quality of the patient's life.
Who: Completed by the patient and reviewed by the RC.

When: Screening Phase, Brief Clinic Visits, and Extensive Clinic Visits.
Instructions:
Because this form is a standardized questionnaire (the SF-36), the procedures created by the developers of this form must be *strictly* adhered to when administering this form. These procedures are as follows:
! This form should be administered *before* the patient sees a provider, so that the interaction between the patient and the provider will not influence the patient's answers.
! If the patient asks for clarification of specific questions on the form, assist the patient by rereading the question *word for word*. Do not try to explain what the question means, but suggest that the patient use her/his own interpretation of the question. A patient should answer the questions *based on what she/he thinks* the questions mean.
! A patient may have trouble with the response choices, such as wanting to respond "does not apply" or "I don't know". In these instances, it is important to guide the patient to select one of the categories by saying something like: "I know that it may be hard for you to think this way, but which of these categories most closely expresses what you are thinking". Do not, however, assist the patient in her/his selection of the response. If the patient does not feel comfortable selecting one of the responses, leave the question blank and indicate the reason in the left margin next to the question.
The following list of "Dos and Don'ts" has been created by the developers of this form. It is *very* important that you adhere to these guidelines:
! Do have the patient complete the form before she/he completes any other health data forms and before she/he sees the physician.
Do **not** discuss the patient's health, health data, or emotions with her/him before she/he completes this form.
! Do be warm, friendly, and helpful.
Do **not** force or command the patient to complete the form.
! Do request and encourage the patient to complete the form.

Do **not** accept an incomplete form without first encouraging the patient to complete unanswered questions.
! Do read and repeat a question verbatim for the patient.
Do **not** interpret or explain a question.
! Do tell the patient to answer a question based on what they think the question means.
Do **not** force or command the patient to complete a particular question.
! Do have the patient complete the form by herself/himself.
Do **not** allow spouses or family members to help the patient complete the form.
! Do encourage the patient to complete all questions.

Do **not** minimize the importance of the form.
! Do thank the patient for completing the form.
! Do inform the patient that she/he will be asked to complete the same form again at other clinic visits.

8.3.22 Screening Sign-Off (SCR)

Purpose: To ensure that the Research Coordinator and the Principal Investigator have verified all screening phase data and that the patient is eligible for the ICDB study; to notify the DCC that the screening phase is complete and a Follow-Up Visit Contact Schedule (FVCS) should be generated.
Who: Completed by the Research Coordinator and the Principal Investigator.
When: Screening Phase.
Instructions:
The last screening phase visit date should be the date of the last screening phase visit where data were collected. This date should correspond to the latest visit date on any of the screening data forms.

8.3.23 Symptom History (SYMHX)

Purpose: To collect information regarding the patient's symptom history.
Who: Completed by the patient and reviewed by the Research Coordinator.
When: Screening Phase.
Instructions:
Q5: For the ICDB study, a remission must be a period without symptoms no less than 3 months.
Q18: If the patient has had a hysterectomy and had both ovaries removed, then check "yes". If the patient has had a hysterectomy and still has at least part of one ovary and has experienced menopausal symptoms such as hot flashes, vaginal dryness, and/or discomfort when engaging in sexual relations, then check "yes". If the patient has had a hysterectomy and still has at least part of one ovary and has not experienced any menopausal symptoms, then check "no".
If the patient has not had a hysterectomy and has experienced **any** menopausal symptoms, then check "yes"; otherwise check "no". If the patient has not experienced any symptoms, but has had very irregular periods, with the last period within the last 12 months, then check "no". If her last period was greater than 12 months previously, check "yes".

8.3.24 Symptom Questionnaire (SYMPH)

Purpose: To collect information regarding the patient's urinary symptoms.
Who: Administered to the patient by the Research Coordinator.
When: Month 1 Follow-Up Visit and Telephone Contacts.
Instructions:
Q1: One number should be circled. If the patient responds with a range of numbers, ask her/him to clarify the answer by providing *one* number that best describes her/his pain or urgency.
Q2, Q6: For each question, the patient should indicate one response. If the patient indicates multiple responses, ask the patient to choose the *one* response that *best* answers the question.

Q5: Make sure that the response to this question does not conflict with the responses to Q3 and Q4. Clarify any discrepancies with the patient.
Q6: The scale above the table is part of the instructions for the question. The numbers on this scale should *not* be circled.

8.3.25 Symptom Questionnaire (SYMPTS)

Purpose: To collect information regarding the patient's urinary symptoms.
Who: Completed by the patient and reviewed by the Research Coordinator.
When: Screening Phase, Brief Clinic Visits, and Extensive Clinic Visits.
Instructions:
General Instructions: Before giving the patient this questionnaire to complete, review with the patient the body parts described in questions 7-13. The RC should give the patient the laminated pictures depicting the body parts described in these questions for reference while completing this form. The patient will then be able to refer to the pictures while she/he is answering the

questions.
Q1: One number should be circled. If the patient responds using a range of numbers, ask her/him to clarify the answer by providing *one* number that best describes her/his pain or urgency.
Q2, Q6: For each question, the patient should indicate one response. If the patient indicates multiple responses or leaves a question blank, ask the patient to choose the *one* response that *best* answers the question.
Q5: Make sure that the response to this question does not conflict with the responses to Q3 and Q4. Clarify any discrepancies with the patient.
Q11-Q12: Q11 is a female-only question and Q12 is a male-only question. Make sure that these questions are completed or left missing appropriately.
Q14: The scale above the table is part of the instructions for the question. The numbers on this scale should *not* be circled.

Q24: If the patient has had a hysterectomy, then check "no". If the patient has not had a hysterectomy and has had a period within the last 12 months, check "yes"; otherwise, check "no".

8.3.26 Urinalysis (URN)

Purpose: To summarize the information obtained from the dipstick analysis of the urine specimen.
Who: Completed by the Research Coordinator.
When: Screening Phase, Brief Clinic Visits, and Extensive Clinic Visits.
Instructions:
The visit date on this form should correspond to the date that the urine specimen was collected.
Urinalysis results should be transcribed from the dipstick to the data form.

8.3.27 Urodynamic Evaluation (UROD)

Purpose: To summarize the information obtained from the urodynamic evaluation.
Who: Completed by the physician or technician performing the urodynamic evaluation and reviewed by the RC.
When: Screening Phase.
Instructions:
The visit date on this form should correspond to the date that the urodynamic evaluation was performed.
The urodynamic trace must be submitted with the packet of screening phase data forms. Any patient identifying information (i.e., name or hospital ID number) must be removed or covered. The report must contain the red ink laboratory report stamp in the upper or lower right hand corner of the front of the first page. This stamp must indicate the patient ID number, the date that the urodynamic evaluation was *performed*, and the form code "TRACE".

8.3.28 Voiding Log (VOID)

Purpose: To collect information regarding the patient's voiding pattern over a 3-day period.

Who: Completed by the patient and reviewed by the RC.
When: Screening Phase and all follow-up visits.
Instructions:
All three days of the voiding log should be completed within the time window for the visit.
The instructions for the voiding log, listed on page 1 of the form, should be thoroughly reviewed with the patient before she/he completes her/his screening phase log and reviewed at each follow-up visit. If a patient cannot properly complete a screening phase voiding log, the RC should evaluate whether the patient can and/or will adhere to the protocol to warrant enrollment in the study.
All pages of the voiding log should be submitted to the DCC, including the instructions page (page #1). Ensure that the Reviewer ID is completed on page 1.
When a patient returns a voiding log, it should be reviewed thoroughly, in the presence of the patient.
! If the log was not completed for 3 three *consecutive* days (with *exactly one* weekend

day), the instructions should be reviewed and the patient should be asked to repeat the log.

! If the returned voiding log is sloppy or difficult to read, it should be re-copied before being submitted to the DCC. The original patient log should be stapled to the back of the re-copied log. Label the copy "RECOPIED", with your initials and date re-copied.

! Any discrepancies or missing values (including dates, hours, *and* minutes) should be clarified and corrected, if possible. Ensure that the am/pm values are correct and that the times are not indicated on a 24-hour (military) clock.

! Only one number should be circled on each pain and urgency scale. If the patient circled a range of numbers, ask her/him to clarify the answer by providing *one* number that *best* described her/his pain or urgency.

! If the patient does not indicate *any* asterisks (*) for awakening to void, verify with her/him that she/he did not awaken to void.

8.4. INSTRUCTIONS FOR THE COMPLETION OF ADMINISTRATIVE FORMS

8.4.1 General Instructions for Administrative Forms

Instructions for specific administrative forms are contained in Section 8.4.2. The items below are guidelines to be followed when completing any of the administrative forms.

All administrative forms should be completed in **black** ink. Red ink should be used when making corrections to photocopies of forms during the completion of query forms (QDC and QMD) and the Clinic-Initiated Data Correction (CIDC) form.

All responses should be printed legibly. When making changes to answers or correcting mistakes or incorrectly recorded information, put a single line through the middle of the incorrect information. Record the correct information, and initial and date the correct answer. Circle the correct answer for clarification, if necessary.

8.4.2 Specific Instructions for Administrative Forms

This section provides specific instructions for the correct completion of administrative forms. The following information is provided for each form: the purpose of the form, when the form should be completed, and specific instructions. If you are unable to find specific information that you need to complete the form, please contact the ICDB Data Manager.

8.4.2.1. Address Update Form (ADDR)

The Address Update Form (ADDR) provides a simple tool for the RC to keep updated information on all patients involved in the ICDB Study. This form should be completed by the RC whenever the patient's address, phone number, or employer has changed. The form must not be sent to the DCC; it is for Clinical Center records only.

8.4.2.2. Informed Consent Form

The Informed Consent Form, developed by each of the individual Clinics, provides the mechanism for the patient to consent to participating in the ICDB Study. The form **must** be completed by the patient prior to collecting any information or performing any procedures for the specific purpose of the ICDB Study. The form must not be sent to the DCC; it is for Clinical Center records only.

8.4.2.3. Patient Registration Form (REG)

The Patient Registration Form (REG) assigns the patient ID number and provides the RC with a simple tool to keep a record of the addresses, phone numbers, and employers of all patients involved in the ICDB Study. The form must be completed by the patient at her/his first screening visit. The form must not be sent to the DCC; it is for Clinical Center records only.

8.4.2.4. Patient Status Form (STAT)

The Patient Status Form (STAT) is a simple tool designed to help the RC keep track of the status of each patient registered for the ICDB study. This form is optional and may be completed by the RC whenever a patient has a change in status. The form **must** not be sent to the DCC; instead it should be placed in the patient's medical records.

8.4.2.5. Patient Withdrawal Form (WITH)

The Patient Withdrawal Form (WITH) is designed to keep track of all patients who withdraw from the study. This form must be completed by the RC whenever a patient decides that she/he no longer

wants to participate in the study or when a patient is lost-to-follow-up. A copy of the form should be placed in the patient's study book, and the original form should be sent to the DCC in the next mailing.

8.4.2.6. **Patient Reinstatement Form (REIN)**

The Patient Reinstatement Form (REIN) is designed to keep track of patients who previously withdrew from the study and want to be reinstated. This form must be completed by the RC whenever a patient who has been previously withdrawn from the study desires to participate in the ICDB Study again. A copy of the form should be placed in the patient's study book, and the original form should be sent to the DCC in the next mailing.

8.4.2.7. **Request for Forms (FREQ)**

The Clinical Center Request for Forms form (FREQ) should be used any time a Clinical Center wishes to request forms from the DCC. This form requires the Clinical Center ID and name, and the date of request. Forms packets may be ordered by box by contact type. Individual forms may also be ordered. The form should be signed by the requestor prior to being sent to the DCC. The RC should allow 10-15 business days to receive the forms.

8.4.2.8. **Visit Checklists**

A Checklist was created for each visit to provide the RC with a simple way of ensuring that all required data forms and diagnostic procedures were completed. The Visit Checklist should always be checked before a patient leaves the clinic or gets off of the phone. The checklist must accompany the forms packet for that visit when it is mailed to the DCC.

In the "Submitted to DCC?" column, indicate with a checkmark whether or not each form was completed at the clinic. If a form was completed and is in the attached packet, check the "Yes" column. If a form was not completed due to some extenuating circumstance, check the "No" column. If the form is not applicable (e.g. patient is male, so no pregnancy history is completed), then check the "N/A" column.

8.4.2.9. **Visit Reminders**

Visit Reminders should be sent to the patient two weeks before a scheduled visit. The visit reminders should be accompanied by any forms that must be completed by the patient prior to the study visit. Please refer to Section 6.4: *Visit Reminders* for more details.

8.4.2.10. **Biopsy Specimen Tracking Form (TRACK)**

The Biopsy Specimen Tracking Form (TRACK) is designed to track the shipment of the Database Biopsy specimens from the Clinical Center to the Anatomic Pathology Laboratory (APL) and to provide pertinent biopsy information to the APL pathologist. Please refer to the Bladder Biopsy Handling chapter (Section 10.4: *Relevant Biopsy Forms*) of this manual for more details.

8.4.2.11. **Biopsy Slide Tracking Form (SLTR)**

The Biopsy Slide Tracking Form (SLTR) is designed to track the shipment of the Home Institution Biopsy microscope slides from the Clinical Center to the APL and to provide pertinent biopsy information to the APL pathologist. Please refer to the Bladder Biopsy Handling chapter (Section 10.4: *Relevant Biopsy Forms*) of this manual for more details.

8.4.2.12. **Data Clarification Form (QDC)**

The Data Clarification Form (QDC) is a query form initiated at the DCC and sent to the Clinical Center to request clarification of an unclear, illogical, or problematic response on a form. The query form identifies the patient ID, visit type, date of visit, form code, date of query, and an explanation of the question(s) requiring clarification. A photocopy of the appropriate pages of the form are attached to the query form. The queried item should be clarified with the patient, the patient's Study Book, and/or the patient's medical records, as appropriate. The clarification should be indicated either on the query form or the attached photocopy of the form (in red ink). The completed query form should be signed and dated, photocopied for the patient's Study Book, and sent to the DCC in the next mailing. The patient's Study Book and/or the patient's medical records should be updated

to reflect the change indicated on the submitted query form so that the Clinical Center records match those maintained at the DCC. Changes to the patient's Study Book or medical records should be made by crossing out the error with a single line in black ink, entering the correct information, and

initialing and dating the change.

8.4.2.13. **Request for Missing Data (QMD)**

The Request for Missing Data (QMD) is a query form initiated at the DCC and sent to the Clinical Center to request missing data on a form. The query form identifies the patient ID, visit type, date of visit, form code, date of query, and the question number(s) of the missing data. A photocopy of the appropriate pages of the form are attached to the query form. The queried items should be retrieved from the patient, the patient's Study Book, and/or the patient's medical records as appropriate. The missing data should be provided either on the query form or the attached photocopy of the form (in red ink). If the missing data cannot be obtained, the reason should be indicated on the query form. The completed query form should be signed and dated, photocopied for the patient's Study Book, and sent to the DCC in the next mailing. The patient's Study Book and/or the patient's medical records should be updated to reflect the change indicated on the submitted query form so that the Clinical Center records match those maintained at the DCC. Changes to the patient's Study Book or medical records should be made by crossing out the error with a single line in black ink, entering the correct information, and initialing and dating the change.

8.4.2.14. **Clinic-Initiated Data Correction Form (CIDC)**

The Clinic-Initiated Data Correction Form (CIDC) should be used to notify the DCC of any necessary corrections to data already submitted to the DCC. This form should be used for items which cannot be queried or have not been queried and is not intended to be used to record corrections already recorded on a query form. The form requires the patient ID, visit type, date of visit, form code, a brief description of the correction, and the reason for the correction. A photocopy of the applicable pages of the original form should be used to indicate the corrections in red ink and then stapled to the correction form. The completed correction form should be signed and dated, photocopied for the patient's Study Book, and sent to the DCC in the next mailing.

8.5. SUBMISSION OF COMPLETED FORMS TO THE DCC

8.5.1. **Preparing the completed forms to be sent to the DCC**

No forms for a visit should be submitted to the DCC until *all* forms in that visit packet are completed. For the screening phase, visit packets should only be submitted to the DCC if the patient is eligible and has completed the screening phase.

Once a visit pac