Modification of Diet in Renal Disease Study
SCREENING FORM

Complete this form for all patients with chronic renal disease, age 18 to 70, with serum creatinine within the past year between 1.2 and 7.0 mg/dl for females, and between 1.4 and 7.0 mg/dl for males, not taking insulin and not a transplant recipient who have a visit. The form should be completed by the Study Coordinator at the conclusion of the screening visit.

QUESTION #	INSTRUCTIONS
1.	Enter the Patient ID Code assigned to this patient on Form #01.
2.	Enter the patient's Name Code. The first 2 letters of the patient's first name and the first 2 letters of the patient's last name.
3.	Enter the code associated with the Clinical Center where this patient is being evaluated. The following is a list of permanent identification codes for each Center taking part in this study. 01 = Bowman Gray School of Medicine 02 = Brigham and Women's Hospital/Beth Israel Hospital 03 = Brookdale Hospital Medical Center 04 = Duke University School of Medicine 05 = Emory University 06 = George Washington University Medical Center 07 = Harbor Medical Center 08 = New England Medical Center Hospital/ Massachusetts General Hospital 09 = Ohio State University Hospitals 10 = University of Florida 11 = University of Iowa Hospital and Clinics 12 = University of Miami Jackson Memorial Medical Center 13 = University of Southern California 14 = University of Texas Health Science Center 15 = Vanderbilt University Medical Center
4c.	The first Screening visit should be labelled 01.0. If patient is screened a second time enter 02.0.
6.	Items 13-16 are diagnoses made by renal biopsy. Remember if "other" is specified, up to 20 digits of the specification may be entered.
7.	The patient's age is calculated by subtracting the birth date from the date the form is completed.
10.	If the patient is male, enter a 2. If the patient is female, refer to the most recent data recorded in the chart. If she is known to be a lactating mother or pregnant, enter a 1. If she is planning to be pregnant within 2 to 4 years, enter a 1. If not, enter a 2.

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QUESTION #	INSTRUCTIONS
11.	Enter a 1 if the patient is currently enrolled in another study in which diet or drug therapy is stipulated. Enter a 2 if there is no evidence of this.
12.	Final judgment regarding compliance is made by the local Principal Investigator after consultation with the patient's physician. Enter a 1 if any of the items listed is yes. Enter a 2 if not.

a. If there is documented evidence of chronic use of heroin, cocaine, barbiturates or other illicit drugs, enter a 1. If no evidence is found, enter a 2.

b. If the patient's records indicate previous hospitalizations for alcoholism or previous history of arrests for alcohol abuse and there is no demonstration of cessation for the past year, enter a 1. If there is no evidence of abuse or the patient has demonstrated cessation of abuse for at least one year, enter a 2.

c. If there is documented evidence of a history of major psychiatric illness or psychosis requiring hospitalization or treatment by either a psychiatrist or psychotropic drugs within the past year, enter a 1. If no such evidence is apparent, enter a 2.

d. If the patient is illiterate, unable to understand study procedures, enter a 1. Otherwise, enter a 2.

e. If the patient does not appear to be motivated to participate in the study, enter a 1. Otherwise, enter a 2.

f. If the patient has diet preferences which will not allow compliance to study diets, enter a 1. Otherwise, enter a 2.

g. If the patient plans to move from the area in the next two years, enter a 1. Otherwise, enter a 2.

h. If the patient has no cooking facilities, or if the person responsible for the patient's cooking refuses to cooperate, enter a 1. Otherwise, enter a 2.

i. If the patient appears to fail to keep at least half of his or her scheduled appointments as ascertained from previous records, enter a 1. If no such evidence is found, enter a 2.

j. If the patient cannot communicate with study personnel, is unable to write food records, cannot read or is illiterate, enter a 1. Otherwise, enter a 2.

k. If the patient does not have access to a telephone at which he or she can be reached, enter a 1. Otherwise, enter a 2.

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QUESTION	INSTRUCTIONS
12.	1. If the patient exhibits some characteristics which make you feel his or her compliance is doubtful, (i.e., patient refusal) enter a 1. Write in the evidence in the space provided. Otherwise, enter a 2.
	m. If compliance is doubtful for some other reason, enter a 1 here and specify reason.
	If any part of item 12 is yes, the patient is not eligible. However, continue to complete the remainder of the form.
13.	For parts 'a' - 'd', if there is documented evidence that the patient has the specified renal disorder, enter a 1 in the appropriate space. If no evidence is found, enter a 2.
14.	If the patient has urinary retention identified by history, physical or radiologic examination, enter a 1. Otherwise, enter a 2.
15.	a. Enter a 1 if the patient has had metastatic cancer or resection of a primary malignant lesion within the past year (except squamous cell or basal cell carcinoma of the skin). Also, enter a 1 for patients who are undergoing current adjuvant chemotherapy, or for patients who have multiple myeloma or renal disease due to a monoclonal gammopathy. If none of these are documented, enter a 2.
	b. The New York Heart Association functional classes are as follows: Class 1: No symptoms. Class 2: Comfortable at rest. Symptoms with ordinary physical activity. Class 3: Comfortable at rest. Symptoms with less than ordinary physical activity. Class 4: Symptoms at rest. If the patient displays disability from heart failure (>=Class 3) despite therapy with digitalis, diuretics, and afterload reducing agents, enter a 1. If no such evidence is found, enter a 2.
	c. Enter a 1 if the patient demonstrates severe chronic lung disease causing cor pulmonale or requiring steroid therapy. If no such evidence is found, enter a 2.

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QUESTION #	INSTRUCTIONS
15.	d. If two of the patient's serum bilirubin measurements within the past three months are greater than 1.5 mg/dl, enter a 1. If not, or if the patient has Gilbert's disease, enter a 2. If there is evidence of portal hypertension (with or without a known diagnosis of cirrhosis) complicated by edema, enter a 1. If two of the patients SGOTs or other serum transaminases in the past three months have been greater than 100 IU/L, enter a 1. If no such evidence is found or the patient has intermittent asymptomatic elevated transaminases, enter a 2.
	e. Enter a 1 if the patient has any disease requiring treatment with diets which would seriously complicate a low protein diet prescription. If no such evidence is found, enter a 2.
	f. Enter a 1 if the patient has experienced chronic infections requiring prolonged antibiotic therapy within the past six months (i.e., systemic mycoses, AIDS, or active tuberculosis). This does not include uncomplicated urinary tract infections. If no such illnesses have occurred, enter a 2.
	g. Enter a 1 if the patient has a collagen vascular disease such as SLE or vasculitis. Patients with rheumatoid arthritis are not excluded; for these patients, enter a 2. Enter a 2 if none of these diseases are evident.
	h. If the patient has been hospitalized more than three times in the past year, enter a 1. If not, enter a 2.
	i. If the patient has been in the hospital for more than 60 days in the past year, enter a 1. Otherwise, enter a 2.
	j. If the patient is disabled as shown by an inability to perform most activities of daily living (such as dressing, feeding or using a toilet), enter a 1. If not, enter a 2.
16.	If the patient is taking any of the listed medications, enter a 1. Otherwise, enter a 2. a. If the patient is taking immunosuppressive agents, enter a 1. Otherwise, enter a 2.

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QUESTION # INSTRUCTIONS

b. If the patient has taken corticosteroids in excess of 7 milligrams prednisone equivalents daily for two or more months out of the past year, enter a 1. If no evidence of this is found, enter a 2.

	Equivalency	
Cortisol	30 mg	7.5 mg
Cortisone	37.5 mg	7.5 mg
Dexamethasone	1.125 mg	7.5 mg
Triamcinolone	6 mg	7.5 mg
Prednisolone	7.5 mg	7.5 mg
Methylprednisolone	6 mg	7.5 mg

c. If the patient has taken gold within the past month, enter a 1. If no evidence of this is found, enter a 2.

d. If the patient has taken penicillamine within the past month, enter a 1. If no evidence of this is found, enter a 2.

e. If the patient has been taking more than 20 tablets of 325 mg salicylates per week, enter a 1. If no evidence of this is found, enter a 2.

f. If the patient has taken more than the MDRD Maximum Allowable dose of other non-steroidal anti-inflammatory agents within the past two months, enter a 1. If no evidence of this is found, enter a 2. See the attached equivalency chart for maximum allowable dose.

g. If the patient is taking any investigational new drugs, excluding Erythropoietin enter a 1. If no evidence of this is found, enter a 2.

h. Until further notice from the FDA, use of Erythropoietin is an exclusion.

17. If the patient has exhibited a previous allergic reaction following an iothalamate injection or an iodide ion, enter a 1 in the appropriate space. If not, enter a 2.

18. a. Enter the date on which the most recent serum albumin was determined. This date must be within the past three months.

b. Enter the most recent serum albumin value found. The value should be recorded in grams per deciliter, rounded to the nearest tenth, right justified, and zero-filled. If the patient is eligible this must be completed. If the patient is <u>not</u> eligible this may be left blank.

MAXIMUM ALLOWABLE DOSE OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS

PRODUCT NAME	ADVIL	IBUBROFEN	MOTRIN	NUPRIN	RUFEN
Pharmaceutical Firm	Whitehall	Danbury	Upjohn	Bristol	Boots
Active Ingredient	Ibuprofen	Ibuprofen	Ibuprofen	Ibuprofen	Ibuprofen
Tablet Strength	200 mg	400 mg 600 mg	400 mg 600 mg 800 mg	200 mg	400 mg 600 mg
Recommended Dosage	1 tablet q 4-6 h		usual dose: 1200-3200 mg per day Not to exceed 3200 mg per day	Not to exceed 6 tablets unless directed by a physician	Not to exceed 2400 mg per day
Maximum allowable weekly dose based on MDRD study protocol	6-200 mg tablets	3-400 mg tablets 2-600 mg tablets	3-400 mg tablets 2-600 mg tablets	6-200 mg tablets	3-400 mg tablets 2-600 mg tablets

2.30

MAXIMUM ALLOWABLE DOSE OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS

PRODUCT NAME	ANAPROX	CLINORIL	DOLOBID	FELDENE	INDOCIN
Generic Name	Naproxen Na	Sulindac	Diflunisal	Piroxicam	Indomethacin
Tablet Strength	275 mg	150 mg 200 mg	250 mg 500 mg	10 mg 20 mg	25 mg 50 mg 75 mg (Indocin SR) Suppositories available
Recommended Dosage	Max. dosage 1375 mg daily	2 tablets daily with food (400 mg max. daily)	1000 mg initially 500 mg q 12o	20 mg (single daily dose)	max. 100 mg/day
Max. allowable weekly dose based on MDRD study protocol	825 mg (3 tablets)	300 mg (2-150 mg tab)	750 mg (3-250 mg tabs)	15 mg (1-20 mg tabs)	75 mg (3-25 mg tabs)

2.31

MAXIMUM ALLOWABLE DOSE OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS

PRODUCT NAME	NECLOMEN	NAPROSYN	NALFON	PONSTEL	TOLECTIN
Generic Name	Meclofenamate	Naproxen	Fenoprofen	Mefenamic acid	Tolmelin Na
Tablet Strength	50 mg	250 mg 375 mg 500 mg	200 mg 300 mg 600 mg	250 mg	200 mg 400 mg
Recommended Dosage 24o);	200-400 mg/day admin in 3-4 equal doses of 400 mg/day	250 mg 375 mg max. 1250 mg/day	200 mg q 4-6o (Analgesic) 500 mg Rheu Arth 3-4 x daily	500 mg initially 250 mg q 6o mg	400 mg initially tid (1200 mg max. in 300-600 mg then 600-1800 mg divided in 3 except 4 doses/day can be given for
daily					
doses/day					
Rheu					
Arth					
Maximum allowable weekly dose based on MDRD study protocol	300 mg (6 tablets)	375-562 mg tablets	900-1800 mg tablets	938 mg = 4 tablets	900 mg (5-200 mg tablets) 1350 mg (4-400 mg tablets)

2.32

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QUESTION #	INSTRUCTIONS
	c. Enter a 1 if the value in part 'b' is less than 3.0 g/dl. If the serum albumin is greater than or equal to 3.0 g/dl, enter a 2.
19.	Standard Body Weight should be completed by the dietitian. Instructions for its completion are included in the Nutrition portion of the Manual of Operations. If the patient is not eligible, this section may be left blank.
	a. The patient's height should be recorded in centimeters, rounded to the nearest tenth of a centimeter. Only values between 120 and 200 may be entered. Height should be measured twice, both should be recorded and the average used for further calculations. For more specific instructions see the Nutrition portion of the Manual of Operations.
	b. The right elbow breadth should be recorded in centimeters rounded to the nearest tenth.
	c. The patient's frame size is determined from his or her elbow breadth.
	d. The patient's actual body weight should be entered in kilograms, rounded to the nearest tenth. The weight should be measured twice and the average used. Refer to the Nutrition portion of the Manual of Operations for further instructions. The dietician does <u>not</u> have to be the person to complete this item.
	e. The standard weight is determined according to height, sex, and frame size.
	f. (average from part 'd'/answer to part 'e') multiplied by 100. The value should be rounded to a whole percentage point, then right justified.
	g. If the value in part 'f' is greater than or equal to 80% and less than or equal to 160%, then enter a 2. If it is outside this range, enter a 1. The patient is not eligible.
	h. Enter dietitian's certification number.

Modification of Diet in Renal Disease Study
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QUESTION #	INSTRUCTIONS
20.	To be eligible: items 8-17 and 18c must be no, item 19g must be no, MAP must be ≤ 125 and the first creatinine value must be within range (or Form 51 indicates other evidence of renal disease) and within the past month. If item 20 indicates not eligible - DO NOT HOLD A BASELINE VISIT.
21.	If the patient is willing and able to give consent, enter a 1. If not, enter a 2.
101.	Enter the date that the form is completed. Right justify.
102.	Enter your unique certification number. You thus take responsibility, for the accuracy of the data contained in this form.
103.	Enter the date when the form was entered into the computer. This should be the same date that the form was completed, or as soon as possible thereafter.
104.	The data entry person's certification number must be entered. He or she thus takes responsibility for the accuracy of the entered data.
	In completing the creatinine chart be sure the most recent value is first for eligibility determination. If a patient is REscreened, enter only additional creatinine values since the first completion of this form. If there are no new values, repeat the most recent one in the first space provided.
	It is very important to get the past creatinine measurements from the patient's chart. This may involve writing to the patient's physician in another city to obtain data.
	If two creatinines are reported in the chart on the same day, an average value should be entered on the form.
	If creatinines are available during hospitalizations they should be included on page 6. Do not make judgments regarding which values to enter and which not to. Include ALL creatinine values available.
Form 51/ Creatinines	If the patient's creatinine is too low but there is other evidence of renal disease (thus making the patient eligible) you must complete Form 51.
	If the only thing making a patient ineligible is that the creatinine is too low and there is <u>not</u> other evidence of renal disease do the following: item 12 = Yes item 12 m = 1 = Yes item 12 m = NO OTHER EVIDENCE , OR CREATININE IS TOO LOW item 20 = 2 = No

MDRD

Modification of Diet in Renal Disease Study
Screening Form

This form is to be completed at the conclusion of the screening visit on all patients with chronic renal disease, age 18 to 70 years, serum creatinine within the past year between 1.2 and 7.0 mg/dl for females, and between 1.4 and 7.0 mg/dl for males, not taking insulin and not a kidney transplant recipient. For those patients who are eligible, the Baseline Visit 0 must take place within two months of the date of the serum creatinine which determines eligibility.

FORM # 0 3

1. Patient Identification Number ..... ___ ___ ___ ___ ___ ___
2. Patient Name Code ..... ___ ___ ___ ___
3. Clinical Center ..... ___ ___
4. a. Date of Screening Visit ..... ___ ___/ ___ ___/ ___ ___

   b. Visit Type ..... S

   c. Visit Number ..... ___ ___ . ___
5. Sex (1 = male, 2 = female) ..... ___
6. Primary Renal Diagnosis ..... ___ ___

1 = Polycystic kidney disease	15 = Membranoproliferative glomerulonephritis
2 = Hereditary nephritis	
3 = Analgesic nephropathy	16 = Mesangial proliferative glomerulonephritis
4 = Pyelonephritis	
5 = Other interstitial nephritis	17 = Chronic renal failure with proteinuria
6 = Obstructive uropathy - acquired	18 = Nephrotic syndrome without biopsy
7 = Obstructive uropathy - congenital	19 = Absence of one kidney
8 = Vesico-ureteral reflux	20 = IgA nephropathy
9 = Urinary tract stones	21 = Other glomerulonephritis
10 = Hypertensive nephrosclerosis	22 = Other (20 characters maximum)
11 = Diabetic nephropathy	(_____)
12 = Renal artery stenosis	23 = Unknown
13 = Membranous nephropathy	24 = None
14 = Focal sclerosis	

ELIGIBILITY DETERMINATION

7. Patient's age ..... ___ ___
8. Is the patient taking insulin? (1 = yes, 2 = no) ..... ___
9. Is the patient a kidney transplant recipient? (1 = yes, 2 = no) ..... ___
10. Is the patient pregnant or lactating? (1 = yes, 2 = no) ..... ___

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11. Is the patient currently enrolled in another study in which diet or drug therapy is stipulated? (1 = yes, 2 = no) ....___

12. Is compliance doubtful for one or more of the following reasons? (1 = yes, 2 = no) ....___

If yes, (for items a through m, code 1 = yes, 2 = no)

a. drug abuse? ....___

b. alcohol abuse? ....___

c. major psychiatric illness (within past year)? ....___

d. poor understanding of study? ....___

e. limited motivation? ....___

f. unsuitable diet preferences? ....___

g. transient residence? ....___

h. unsuitable home environment? ....___

i. pattern of frequently missed clinic appointments? ....___

j. cannot communicate well? ....___

k. lack of access to a telephone? ....___

l. poor compliance in other clinical trials? ....___

m. other (20 characters maximum)(_____)..___

13. Does the patient have any of the following known and documented renal disorders? (1 = yes, 2 = no) ....___

If yes, (for items a through d, code 1 = yes, 2 = no)

a. urinary tract obstruction ....___

b. renal artery stenosis as the cause of renal insufficiency ....___

c. branched or staghorn calculi ....___

d. cystinuria ....___

14. Does the patient have documented or known evidence of urinary retention? (1 = yes, 2 = no) ....___

Modification of Diet in Renal Disease Study
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15. Does the patient have any of the following known and documented chronic serious medical conditions? (1 = yes, 2 = no) ....___

If yes, (for items a through j, code 1 = yes, 2 = no)

a. malignancy (within the past year - exclude skin) ....___

b. heart disease NYHA class 3 or 4? ....___

c. severe chronic lung disease ....___

d. clinically significant liver disease ....___

e. gastrointestinal disease (which affects diet or nutrition) ....___

f. chronic systemic infections (within past six months) ....___

g. collagen vascular disease (except for rheumatoid arthritis) ....___

h. Has the patient been hospitalized more than three times in the past year? ....___

i. Has the patient been in hospital more than 60 days within the past year? ....___

j. Is the patient disabled? ....___

16. Is the patient taking any of the following medications? (1 = yes, 2 = no) ....___

If yes (for items a through h, code 1 = yes, 2 = no)

a. immunosuppressive agents ....___

b. corticosteroids ....___

c. gold (within past month) ....___

d. penicillamine (within past month) ....___

e. salicylates ....___

f. other non-steroidal anti-inflammatory agents ....___

g. investigational new drugs (excluding Erythropoietin) ....___

h. Erythropoietin ....___

17. Does the patient have a known allergy or adverse reaction to iodine or iothalamate? (1 = yes, 2 = no) ....___

Modification of Diet in Renal Disease Study
Screening Form

18. Serum albumin
    a. Date of most recent serum albumin
    (must be within the past three months) ..... ___ ___/ ___ ___/ ___ ___

    b. Most recent serum albumin (g/dl) ..... ___ . ___

    c. Is most recent value less than 3.0 g/dl? (1 = yes, 2 = no) ..... ___

NOTE: If any of the answers to questions 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, or 18c is yes, the patient is not eligible. Item 19 does NOT need to be completed. Skip to item 20.

If eligible thus far complete items 19 onward.

FOR ALL PATIENTS, COMPLETE THE CHART OF CREATININE VALUES AND DATES ON PAGE 5.

19. Standard Body Weight (to be provided by dietitian)
    a. height (cm) 1.) ..... ___ ___ ___ . ___
    2.) ..... ___ ___ ___ . ___

    b. elbow width (cm) 1.) ..... ___ . ___
    2.) ..... ___ . ___

    c. frame size ..... ___
    1 = Small
    2 = Medium
    3 = Large

    d. body weight (kg) 1.) ..... ___ ___ ___ . ___
    2.) ..... ___ ___ ___ . ___

    e. standard weight (kg) ..... ___ ___ ___ . ___

    f. percentage of standard weight (%) ..... ___ ___ ___

    g. Is the percentage of standard weight outside the allowable range (80% -160%)? (1 = yes, 2 = no) ..... ___

    h. certification number of dietitian ..... ___ ___ ___ ___ ___

Complete Form 46 to record Patient Blood Pressure.
MAP must be ≤125 for patient to be eligible.

20. Does the patient meet ALL eligibility requirements? (Items 8 - 17, 18c are no, 19g = no, MAP ≤125 from Blood Pressure Form and 1st Creatinine within range) (1 = yes, 2 = no) .... ___

21. Is the patient willing and able to give consent? (1 = yes, 2 = no) ..... ___

The patient is eligible to enter Baseline if items 20 and 21 are both yes.

Be sure the patient has signed the Primary (Baseline) Informed Consent, and schedule the Baseline Visit 0 within two months.

If the patient is eligible, but will not consent to enter baseline (item 20 = yes and 21 = no), the patient is no longer followed.

Modification of Diet in Renal Disease Study
Screening Form

101. Date this form completed..... ___ ___/ ___ ___/ ___ ___

102. Certification number of person filling out this form ..... ___ ___ ___ ___ ___

103. Date form entered..... ___ ___/ ___ ___/ ___ ___

104. Certification number of data entry person ..... ___ ___ ___ ___ ___

Modification of Diet in Renal Disease Study
Screening Form

TABLE 1: REVIEW OF SERUM CREATININE

Record all serum creatinines in the last three years from the most recent to the earliest. Complete these items by going down Column 1 first and then continuing with Column 2.

COLUMN 1		COLUMN 2	
Serum Creatinine (mg/dl)	Date	Serum Creatinine (mg/dl)	Date
** ___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___
___ ___ . ___	___ ___/___ ___/___ ___	___ ___ . ___	___ ___/___ ___/___ ___

** **The Baseline Visit 0 must be within two months of this date.**