MYELOMA FORMS

The guidelines and figures below are specific to Myeloma studies. The information in this manual does NOT represent a complete set of required forms for any myeloma study. Please refer to the most recent version of the appropriate protocol for complete forms and submission requirements.

Multiple Myeloma Onstudy Guidelines

Disease History and Diagnosis

*Date of First Pathologic Diagnosis:* This is the date the first histological/cytological diagnosis of the malignancy was obtained, even when the determination is made on review of evidence previously read as benign. In the absence of an exact date the following estimates may be used; indicate that the date coded is an estimate in the Comments section.

1. Date of admission when it is known that the diagnosis was made within one month prior to hospital admission.
2. Date of admission when malignancy was diagnosed during that hospital admission.
3. Date of first therapy for the malignancy.

*Diagnosis:* Record the specific diagnosis of the patient’s disease.

Patient and Disease Description

*Performance Status:* Please refer to the Commonly Coded Variables in General Forms & Guidelines, chapter 16.

Prestudy Laboratory Values

Record the laboratory values obtained prior to registration. Always use the lab test units specified on forms.

Prior Treatment Related to this Cancer

Prior treatment refers to any disease-related treatment that the patient received prior to registration on the current protocol. Prior treatment pertains only to the cancer being treated on protocol, not other diseases or malignancies the patient may have had.

*Prior Therapy Types:* This item records any agents or substances given to a patient for treatment of their cancer. The therapy must be administered with the intent of affecting, destroying, controlling or changing malignant tissue. Systemic therapy includes chemotherapy agents, hormones, antihormones, endocrine surgery/ablation, immunotherapy agents, or biologic response modifiers.

For purposes of SWOG, the term *systemic therapy* applies to therapies administered by any route including, but not limited to, the following: oral, intraarterial, intramuscular, intravenous, regional perfusion, intrallesional, or local application.
**Treatment Description**: Record the agents included in the therapy regimen. Enter combination therapy, e.g., CMFVP, POMP, VMCP, as one item using standard regimen and drug name abbreviations. Record any specific or unusual details regarding the therapy under Comments.

**How many regimens**: A regimen may include several treatments. For example, 3 courses of an induction treatment followed by a year of maintenance is a simple regimen.

**Stop Date**: Record the month, day and year the therapy was stopped. For combination agent regimens, record the date on which all regimen agents were discontinued.

**Baseline & Follow-up Tumor Assessment Form for Multiple Myeloma**

**Serum M-Protein**

**Date of SPEP**: Record the date that the serum protein electrophoresis test was done.

**Serum M-Protein Spike**: Indicate the results of the serum protein electrophoresis test by recording the value of the serum M-protein in g/dl.

**Date of Immunofixation**: Record the date that the serum immunofixation electrophoresis test was done.

**Serum M-Protein by Immunofixation**: Indicate the results of the serum immunofixation electrophoresis test by choosing either negative, if serum M-protein was not detected by the test, or positive, if serum M-protein was detected by this test.

**Serum Free Light Chains (by Freelite test)**: Record the values of the serum kappa free light chain, serum lambda free light chain, and the kappa/lambda free light chain ratio, as assessed by the serum Freelite test.

**Serum Heavy Chain (select one)**: Indicate the serum M-protein heavy chain that was identified by serum protein electrophoresis or immunofixation.

**Serum Light Chain (select one)**: Indicate the serum M-protein light chain that was identified by serum protein electrophoresis or immunofixation.

Kappa/lambda ratio: Indicate the Kappa/lambda ratio from the identified from the Kappa and Lambda values.

Kappa/lambda difference (dFLC): Obtained by subtracting the concentration of the normal light chain type from the concentration of the abnormal light chain type.
Urine M-Protein

**Date of UPEP:** Record the date that urine protein electrophoresis of the 24-hour urine specimen was done. Urine protein electrophoresis done on random urine specimens are not reliable and M-component protein results from these tests will not be accepted.

**Urine M-Protein Light Chain Excretion:** Indicate the results of the urine protein electrophoresis test done on the 24-hour urine specimen by recording the value of the urine M-protein in mg/24hr.

**Date of Immunofixation:** Record the date that the urine immunofixation electrophoresis test was done.

**Urine M-Protein by Immunofixation:** Indicate the results of the urine immunofixation electrophoresis test by choosing either negative, if urine M-protein was not detected by the test, or positive, if urine M-protein was detected by this test.

**Urine Volume:** Record the volume of the 24-hour urine specimen in ml/24hr.

**Urine Total Protein:** Record the total amount of protein found in the 24-hour urine specimen in mg/24hr.

**Urine Light Chain:** Indicate the urine M-protein light chain that was identified by urine protein electrophoresis or immunofixation.

Bone Marrow Plasmacytosis

**Bone Marrow Biopsy:** Record the date and type(s) of the bone marrow biopsy.

**Marrow Cellularity (%):** Record the percentage of the bone marrow sample that was comprised of cells. This value is typically obtained from the bone marrow core biopsy.

**Plasma Cells on Biopsy (%):** Record the percentage of the bone marrow cells that were comprised of plasma cells.

**Monoclonal Cells in Bone Marrow:** Indicate whether malignant plasma cells were present or absent in the bone marrow. Monoclonal cells must be absent from the bone marrow for a patient to qualify as having a Stringent Complete Response.

Bone Disease

**Serum Calcium:** Record the date and value, in mg/dl, of the lowest serum calcium level measured during this disease assessment.

**Bone Lesions on Skeletal Survey:** Record the date and findings from the skeletal survey or plain X-ray films (not radioisotope bone scan).
Number of Lytic Lesions: Indicate the number of lytic lesions present by checking one of the boxes. Select “Osteoporosis” when the results of the skeletal survey revealed evidence of osteoporosis, but no evidence of lytic lesions.

Compared to last survey, bone health is: Indicate if the patient’s bone health on this skeletal survey is better, stable, or worse when compared to the last skeletal survey done. This field does not need to be completed when filling out a baseline form, but is required on follow up forms when a skeletal survey has been done.

Plasmacytomas

Soft Tissue Plasmacytomas: Indicate if the patient was examined for soft tissue plasmacytomas, and whether or not any plasmacytomas were present. If the patient was not examined, please select “not done.” If the patient was examined, please select “no” if no plasmacytomas were present, or select one of the “yes” options if plasmacytomas were present. When completing a baseline form, the simple “yes” option is acceptable. But when completing a follow up form, if plasmacytomas were present, please select one of the three “yes” options that specify if the plasmacytomas were new, previously existing, or both.

Please record the requested information for all plasmacytomas present: If plasmacytomas were present, please record their characteristics in the spaces provided. If the plasmacytomas are present on multiple assessments, always record them in the same order on each assessment form.

Lesion Number: A lesion number (P1, P2 etc.) is assigned to each plasmacytoma present. If a plasmacytoma is present on multiple assessments, make sure that it always has the same lesion number on each of the assessment forms submitted.

Site of Lesion: Give a brief description of where the plasmacytoma is located.

Greatest Measurement/Greatest Perpendicular Measurement: Record the cross diameter measurements of the plasmacytoma in cm.

Assessment Date: Record the date that the plasmacytoma was assessed.

Amyloidosis and LCDD Prestudy Guidelines

Disease History and Diagnosis

Date of First Pathologic Diagnosis: This is the date the first histological/cytological diagnosis of the malignancy was obtained, even when the determination is made on review of evidence previously read as benign. In the absence of an exact date the following estimates may be used; indicate that the date coded is an estimate in the Comments section.

1. Date of admission when it is known that the diagnosis was made within one month prior to hospital admission.
2. Date of admission when malignancy was diagnosed during that hospital admission.
3. Date of first therapy for the malignancy.

**Date of Pretreatment Assessment**: Record the date the pre-treatment staging work-up was begun, i.e., the date of the first procedure done in the process of staging the patient prior to initiation of the first course of therapy. This may be the date of blood chemistries, X-ray examination, or other laboratory studies.

**Current Disease Information**

**Performance Status**: Please refer to the Commonly Coded Variables in General Forms & Guidelines, Chapter 16.

**Bone Marrow Plasmacytosis**: Record the percentage of the bone marrow cells that was comprised of plasma cells. If both a bone marrow aspirate and a bone marrow core biopsy were done, and both of these samples report different plasma cell percentages, please record the higher plasma cell percentage.

**Bone Lesions on Skeletal Survey**: Record the findings from the skeletal survey or plain X-ray films (not radioisotope bone scan) done at time of registration on protocol.

- **None**: When the skeletal survey reported no evidence of lytic lesions or osteoporosis.
- **Osteoporosis**: When the results of the skeletal survey revealed evidence of osteoporosis, but no evidence of lytic lesions.
- **1-3 Lytic Lesions**: When the skeletal survey reported evidence of three or fewer lytic lesions. This includes cases with evidence of osteoporosis in addition to the lytic lesions.
- **>3 Lytic Lesions**: When the skeletal survey reported evidence of more than three lytic lesions. This includes cases with evidence of osteoporosis in addition to the lytic lesions.

**M-component Data**

This section is used to record information regarding the M-component value from laboratory tests done prior to registration on protocol.

**Serum Heavy Chain**: Record the serum heavy chain which was identified on serum protein electrophoresis or immunofixation.

- **None**: when there was no quantitative immunoglobulin type out of normal range. This includes instances where the patient has non-secretory myeloma or light chain only (Bence-Jones-only) myeloma.

**Serum Light Chain**: Record the serum light chain which was identified on serum protein electrophoresis or immunofixation.
Urine Light Chain: Record the urine light chain which was identified on urine electrophoresis or immunofixation.

Serum Protein Electrophoresis

Total Protein: Record the total protein value in g/dl, rounded to the nearest tenth.

Albumin: Record the value of the protein albumin in g/dl, rounded to the nearest hundredth.

M-Component: Record the value of the M-component protein in gm/dl, as measured by serum protein electrophoresis.

Urine Protein Electrophoresis

This section reports information from the 24-hour urine sample taken prior to registration on protocol. Random urine test are not reliable and M-protein excretion results from these tests will not be accepted.

Urine Volume: Record the 24-hour urine volume expressed in milliliters per day (24-hours).
If the volume is reported in liters per day (l/day), convert to milliliters per day (ml/day) by moving the decimal point three places to the right, i.e., 2.35 liters would be reported as 2350 milliliters.

Total Urine Protein: Record the value of 24-hour urine protein present in the 24-hour urine specimen, expressed as grams per day (24-hours) and rounded to the nearest tenth. If the urine protein is reported in milligrams per day (mg/day), convert to grams per day (g/day) by moving the decimal point three places to the left, i.e., 9520 milligrams would be reported as 09.5 grams.

M-component Excretion: Record the value of M-component protein present in the 24-hour urine specimen, (as measured by urine electrophoresis) expressed as grams per day and rounded to the nearest tenth. If the urine M-component is reported in milligrams per day (mg/day), convert to grams per day (g/day) by moving the decimal point three places to the left, i.e., 4680 milligrams would be reported as 04.7 grams.

Liver

Estimated Liver Span: Record the estimated liver span, expressed as centimeters rounded to the nearest tenth, the method used, and date of this assessment.

Alkaline Phosphate: Record the alkaline phosphate value, expressed in units/L rounded to the nearest tenth, and the date that this value was obtained.

Prestudy Laboratory Values

Record the laboratory values obtained prior to registration.

Presenting Syndrome

For each syndrome that the patient expresses, indicate if the syndrome is “clinical only,” “clinical – biopsy negative,” or “pathologic – biopsy positive.”
Bone Marrow Biopsy
Indicate the extent, if any, of amyloid involvement in the bone marrow.

Echocardiogram
Record the ejection fraction, left ventricular wall thickness, and indicate the level of cardiac amyloid involvement.

Prior Treatment Related to Amyloid
Prior treatment refers to any disease-related treatment that the patient received prior to registration on the current protocol. Prior treatment pertains only to the cancer being treated on protocol, not other diseases or malignancies the patient may have had.

Prior Systemic Therapy: This item records any agents or substances given to a patient for treatment of their cancer. The therapy must be administered with the intent of affecting, destroying, controlling or changing malignant tissue. Systemic therapy includes chemotherapy agents, hormones, antihormones, endocrine surgery/ablation, immunotherapy agents, or biologic response modifiers.

For purposes of SWOG, the term systemic therapy applies to therapies administered by any route including, but not limited to, the following: oral, intraarterial, intramuscular, intravenous, regional perfusion, intralesional, or local application.

Treatment Description: Record the agents included in the therapy regimen. Enter combination therapy, e.g., CMFVP, POMP, VMCP, as one item using standard regimen and drug name abbreviations. Record any specific or unusual details regarding the therapy under Comments.