STAGE I/FAVORABLE HISTOLOGY (FH)
STAGE I/FOCAL OR DIFFUSE ANAPLASIA;
STAGE II/FAVORABLE HISTOLOGY

ROADMAP - REGIMEN EE4A

Patient name: _____ NWTSG #_____

Revised Form? _____ 0=No 1=Yes Investigator: _____

Treatment Start Date: _____/_____/_____ Institution: _____
mm dd yy

Date Last Contact: _____/_____/_____
mm dd yy

At end of week 3 and within two weeks after off treatment, complete form and mail one copy to the DSC.

Ht._____cm. Wt.*_____kg. M^2_____

Year: _____

Week/Date Therapy:	Record Dosages (mg)			HX/PE Wt/BP	Lab/Imaging Studies
0/_____	_____ AMD			X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, CHEST CT, ABD U/S
1/_____		_____ VCR			CBC W/DIFF
2/_____		_____ VCR			CBC W/DIFF
3/_____	_____ AMD	_____ VCR			CBC W/DIFF, SGPT, ALK PHOS, T.BILI
4/_____		_____ VCR			CBC W/DIFF
5/_____		_____ VCR			CBC W/DIFF
6/_____	_____ AMD	_____ VCR		X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CHEST CT**, ABD U/S
7/_____		_____ VCR			CBC W/DIFF
8/_____		_____ VCR			CBC W/DIFF
9/_____	_____ AMD	_____ VCR		X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI
10/_____		_____ VCR			CBC W/DIFF
11/_____					CBC W/DIFF
12/_____	_____ AMD	_____ VCR*		X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI
13/_____					CBC W/DIFF
14/_____					CBC W/DIFF
15/_____	_____ AMD	_____ VCR*		X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, ABD U/S
16/_____					CBC W/DIFF
17/_____					CBC W/DIFF
18/_____	_____ AMD	_____ VCR*		X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI
19/_____					CBC W/DIFF
20/_____					CBC W/DIFF
21/_____				X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, CHEST CT**, ABD U/S

Code up to six (6) most important complications occurring during the above dates (i.e., grade 3 or 4, or any event causing change of therapy). Code blood counts if they cause delay, decrease, or change of therapy. See Appendix III for toxicity criteria and codes.

RECORD TOXICITY TYPE, SEVERITY GRADE, AND DATES

Type			Grade	Onset	Max	Clear	Comments:
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	

If patient has delay or interruption of therapy for psychosocial or environmental reasons, use code 999.

Call coordinator for any grade 4 CNS toxicity, any fatal toxicity, and/or if patient goes off treatment for any reason other than relapse. (see Section 8.0 for studies to be obtained at relapse.)

Code only data occurring weeks 1-21. **OBTAIN OTHER STUDIES AS NEEDED FOR GOOD PATIENT CARE.**

* See Chemotherapy Guidelines on Page 2 for dosage modifications.
** Chest computed tomography should be repeated if lesions were identified on the pre-treatment chest CT, and the pretreatment CXR's were normal.

Eligibility Requirements: See protocol section 3.0.

Specimens for Histologic Review: See protocol section 5.111 and 5.14.

Specimens for Biologic Studies: See protocol section 5.112.

Staging Criteria: See protocol section 5.2.

Pre-treatment Evaluation: See protocol section 5.6.

CHEMOTHERAPY GUIDELINES **(Note: The day of nephrectomy will be considered day 0;** the first dose of chemotherapy will be measured in days from that starting point.) No dose of dactinomycin should be initiated if the absolute neutrophil count is <1,000/mm^3 or the platelet count is <100,000/mm^3.

Babies ≤11 months of age should receive ONE-HALF of the recommended dose of all chemotherapeutic agents, as calculated on the basis of body weight. Full doses of chemotherapeutic agents should be administered to these patients when the child is ≥12 months of age.

STAGE I/FH, FOCAL OR DIFFUSE ANAPLASIA; AND STAGE II/FH: Nephrectomy, chemotherapy using Regimen EE4A (see below):

Dactinomycin (AMD) 0.045 mg/kg/dose IV push (maximum dose - 2.3 mg), beginning within 5 days post-nephrectomy (during week 0), and then at weeks 3, 6, 9, 12, 15, and 18. **The dose of dactinomycin is 1.35 mg/$M^2$for all patients who weigh more than 30 kilograms, but no single dose should exceed 2.3 mg.**

Vincristine (VCR) 0.05 mg/kg IV push (maximum dose - 2 mg), beginning day 7 post-nephrectomy (week 1) if peristalsis has been established; then weekly for a total of 10 doses. **The dose of vincristine is 1.5 mg/M^2 IV push for all patients who weigh more than 30 kilograms, but no single dose should exceed 2.0 mg.**

Vincristine (VCR) 0.067 mg/kg IV push (maximum dose - 2.0 mg) with dactinomycin at weeks 12, 15 and 18. **The dose of vincristine is 2.0 mg/M^2 IV push with dactinomycin for all patients who weigh more than 30 kilograms, but no single dose should exceed 2.0 mg.**

Criteria for Modification of Therapy: See protocol section 6.6.

Toxicity Criteria and Codes: See protocol Appendix III.

Adverse Drug Reaction or Death On Study: See protocol section 7.22.

Examinations After Completion of Therapy: See protocol section 5.72.

Off Treatment Procedures: See protocol section 8.0.

STAGE III & IV/FAVORABLE HISTOLOGY (FH); STAGE II-IV/FOCAL ANAPLASIA

ROADMAP - REGIMEN DD4A

Patient name: _____ NWTSG #_____

Revised Form? _____ 0=No 1=Yes Investigator: _____

Treatment Start Date: _____/_____/_____ Institution: _____
mm dd yy

Date Last Contact: _____/_____/_____
mm dd yy

At end of week 3 and within two weeks after off treatment, complete form and mail one copy to the DSC.

Ht._____cm. Wt.*_____kg. M^2_____

Year: _____

Week/Date Therapy: Record Dosages (mg)				HX/PE Wt/BP	Lab/Imaging Studies
0/_____	_____ AMD		XRT	X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, CHEST CT, ABD CT, ABD U/S, MUGA/ECHO
1/_____		_____ VCR			CBC W/DIFF
2/_____		_____ VCR			CBC W/DIFF
3/_____		_____ VCR	_____ DOX*	X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI
4/_____		_____ VCR			CBC W/DIFF
5/_____		_____ VCR			CBC W/DIFF
6/_____	_____ AMD*	_____ VCR		X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI
7/_____		_____ VCR			CBC W/DIFF
8/_____		_____ VCR			CBC W/DIFF
9/_____		_____ VCR	_____ DOX*	X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, CHEST CT**, ABD U/S
10/_____		_____ VCR			CBC W/DIFF
11/_____					CBC W/DIFF
12/_____	_____ AMD	_____ VCR*		X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI
13/_____					CBC W/DIFF
14/_____					CBC W/DIFF
15/_____		_____ VCR*	_____ DOX*	X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI,
16/_____					CBC W/DIFF
17/_____					CBC W/DIFF
18/_____	_____ AMD	_____ VCR*		X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI
19/_____					CBC W/DIFF
20/_____					CBC W/DIFF
21/_____		_____ VCR*	_____ DOX*	X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, ABD U/S, MUGA/ECHO
22/_____					CBC W/DIFF
23/_____					CBC W/DIFF
24/_____	_____ AMD	_____ VCR*		X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI
25/_____					CBC W/DIFF
26/_____					CBC W/DIFF
27/_____				X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, CHEST CT**, ABD U/S

Code up to six (6) most important complications occurring during the above dates (i.e., grade 3 or 4, or any event causing change of therapy). Code blood counts if they cause delay, decrease, or change of therapy. See Appendix III for toxicity criteria and codes.

RECORD TOXICITY TYPE, SEVERITY GRADE, AND DATES

Type			Grade	Onset	Max	Clear	Comments:
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	

If patient has delay or interruption of therapy for psychosocial or environmental reasons, use code 999.

Call coordinator for any grade 4 CNS toxicity, any fatal toxicity, and/or if patient goes off treatment for any reason other than relapse. (see Section 8.0 for studies to be obtained at relapse.) Code only data occurring weeks 1-27. **OBTAIN OTHER STUDIES AS NEEDED FOR GOOD PATIENT CARE.**

* See Chemotherapy Guidelines on Page 2 for dosage modifications.

** Chest CT should be repeated if lesions were identified on the pre-treatment chest CT, and the pretreatment CXR's were negative.

ROADMAP FOR REGIMEN DD4A, cont'd.

Eligibility Requirements: See protocol section 3.0.

Specimens for Histologic Review: See protocol section 5.111 and 5.14.

Specimens for Biologic Studies: See protocol section 5.112.

Staging Criteria: See protocol section 5.2.

Pre-treatment Evaluation: See protocol section 5.6.

CHEMOTHERAPY GUIDELINES **(Note: The day of nephrectomy will be considered day 0;** the first dose of chemotherapy will be measured in days from that starting point.) No dose of dactinomycin or doxorubicin should be initiated if the absolute neutrophil count is $<1,000/mm^3$ or the platelet count is $<100,000/mm^3$.

Babies ≤11 months of age should receive ONE-HALF of the recommended dose of all chemotherapeutic agents, as calculated on the basis of body weight. Full doses of chemotherapeutic agents should be administered to these patients when the child is ≥12 months of age.

STAGE III/FH; STAGES II OR III/FOCAL ANAPLASIA: Nephrectomy, abdominal irradiation, chemotherapy using Regimen DD-4A (below):

STAGE IV/FH OR FOCAL ANAPLASIA: Nephrectomy, abdominal irradiation according to the local stage of the renal tumor, bilateral pulmonary irradiation, chemotherapy using Regimen DD-4A (see below). Trimethoprim/sulfamethoxazole (TMX) prophylaxis - 2.5 mg/kg bid on three consecutive days per week from the start of therapy, continuing for six months after chemotherapy is complete.

Dactinomycin (AMD) 0.045 mg/kg/dose IV push (maximum dose - 2.3 mg), beginning within 5 days post-nephrectomy (during week 0), and then at weeks 6, 12, 18, and 24. **The dose of dactinomycin administered at week 6 should be decreased by 50% (0.0225 mg/kg/dose) if whole lung or whole abdomen radiation therapy has been given. The dose of dactinomycin is 1.35 mg/M^2 for all patients who weigh more than 30 kilograms, but no single dose should exceed 2.3 mg. The dose of dactinomycin administered at week 6 should be decreased by 50% (0.675 mg/M^2) if whole lung or whole abdomen radiation therapy has been given.**

Vincristine (VCR) 0.05 mg/kg IV push (maximum dose - 2 mg), beginning day 7 post-nephrectomy (week 1) if peristalsis has been established, then weekly for a total of 10 doses. **The dose of vincristine is 1.5 mg/M^2 IV push for all patients who weigh more than 30 kilograms, but no single dose should exceed 2.0 mg.**

Vincristine (VCR) 0.067 mg/kg IV push (maximum dose - 2 mg) with dactinomycin or doxorubicin at weeks 12, 15, 18, 21 and 24. **The dose of vincristine is 2.0 mg/M^2 IV push for all patients who weigh more than 30 kilograms, but no single dose should exceed 2.0 mg.**

Doxorubicin (DOX) 1.5 mg/kg IV push, is given at weeks 3 and 9; subsequently, doxorubicin 1.0 mg/kg IV push is given at weeks 15 and 21. **The dose of doxorubicin administered at week 3 should be decreased by 50% (0.75 mg/kg) if whole lung or whole abdomen radiation therapy has been given. The dose of doxorubicin at weeks 3 and 9 is 45 mg/M^2 IV push, and at weeks 15 and 21 is 30 mg/M^2 IV push for all patients who weigh more than 30 kilograms. The dose at week 3 should be decreased by 50% (22.5 mg/M^2) if whole lung or whole abdomen radiation therapy has been given.**

Criteria for Modification of Therapy: See protocol section 6.6.

Toxicity Criteria and Codes: See protocol Appendix III.

Adverse Drug Reaction or Death On Study: See protocol section 7.22.

Examinations After Completion of Therapy: See protocol section 5.72.

Off Treatment Procedures: See protocol section 8.0 (p. 63-64).

STAGE I-IV/RHABDOID TUMOR OF THE KIDNEY (RTK)
ROADMAP - REGIMEN RTK

Patient name: _____ NWTSG #_____

Revised Form? _____ 0=No 1=Yes Investigator: _____

Treatment Start Date: _____/_____/_____ Institution: _____
mm dd yy

Date Last Contact: _____/_____/_____
mm dd yy

At end of week 3 and within two weeks after off treatment, complete form and mail one copy to the DSC.

Ht._____cm. Wt.*_____kg. M^2_____

Year: _____

Week/Date Therapy: Record Dosages (mg)					HX/PE Wt/BP	Lab/Imaging Studies
0/_____	_____ CBDCA	_____ E			X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, ABD U/S, CHEST CT, MRI OF BRAIN
1/_____						CBC W/DIFF
2/_____						CBC W/DIFF
3/_____	_____ CBDCA	_____ E				CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A
4/_____						CBC W/DIFF
5/_____						CBC W/DIFF
6/_____			_____ CTX XRT		X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A
7/_____						CBC W/DIFF
8/_____						CBC W/DIFF
9/_____	_____ CBDCA	_____ E			X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, ABD U/S
10/_____						CBC W/DIFF
11/_____						CBC W/DIFF
12/_____	_____ CBDCA	_____ E			X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A
13/_____						CBC W/DIFF
14/_____						CBC W/DIFF
15/_____			_____ CTX		X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A
16/_____						CBC W/DIFF
17/_____						CBC W/DIFF
18/_____	_____ CBDCA	_____ E			X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A
19/_____						CBC W/DIFF
20/_____						CBC W/DIFF
21/_____	_____ CBDCA	_____ E			X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, ABD U/S
22/_____						CBC W/DIFF
23/_____						CBC W/DIFF
24/_____			_____ CTX		X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A
25/_____						CBC W/DIFF
26/_____						CBC W/DIFF
27/_____					X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, ABD U/S, MRI OF BRAIN

*** See Chemotherapy Guidelines on page 2 for dosage modifications.**

Code up to six (6) most important complications occurring during the above dates (i.e., grade 3 or 4, or any event causing change of therapy). Code blood counts if they cause delay, decrease, or change of therapy. See Appendix III for toxicity criteria and codes.

RECORD TOXICITY TYPE, SEVERITY GRADE, AND DATES

Type			Grade	Onset	Max	Clear	Comments:
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	

If patient has delay or interruption of therapy for psychosocial or environmental reasons, use code 999.

Call coordinator for any grade 4 CNS toxicity, any fatal toxicity, and/or if patient goes off treatment for any reason other than relapse. (see Section 8.0 for studies to be obtained at relapse.)

Code only data occurring weeks 1-27. **OBTAIN OTHER STUDIES AS NEEDED FOR GOOD PATIENT CARE.**

.

Eligibility Requirements: See protocol section 3.0.

Specimens for Histologic Review: See protocol section 5.111 and 5.14.

Specimens for Biologic Studies: See protocol section 5.112.

Staging Criteria: See protocol section 5.2.

Pre-treatment Evaluation: See protocol section 5.6.

CHEMOTHERAPY GUIDELINES (Note: The day of nephrectomy will be considered day 0; the first dose of chemotherapy will be measured in days from that starting point.) No dose of doxorubicin or carboplatin, and no course of cyclophosphamide or etoposide should be initiated if the absolute neutrophil count is <1,000/mm^3 or the platelet count is <100,000/mm^3.

Babies ≤11 months of age should receive ONE-HALF of the recommended dose of all chemotherapeutic agents, as calculated on the basis of body weight. Full doses of chemotherapeutic agents should be administered to these patients when the child is ≥12 months of age.

STAGES I-IV/RHABDOID TUMOR OF THE KIDNEY: Nephrectomy, radiation therapy and chemotherapy with cyclophosphamide, MESNA, etoposide and carboplatin using **Regimen RTK** (see below):

Carboplatin (CBDCA) 16.7 mg/kg/day x 2 days, IV at weeks 0, 3, 9, 12, 18, 21. **The dose of carboplatin is 500mg/M^2/day x 2 days for all patients who weigh more than 30 kilograms.**

Etoposide (E) (VP-16) 3.3 mg/kg/day x 3 days in 200 cc/M^2 of D5/ 1/2 NS as an IV infusion over 60 minutes daily is given at weeks 0, 3, 9, 12, 18, 21 after carboplatin infusion. **The dose of etoposide is 100 mg/M^2/day x 3 days for all patients who weigh more than 30 kilograms.**

Cyclophosphamide (CTX) 14.7 mg/kg/day x 5 days in 200 cc/M^2 of D5/ 1/2 NS as an IV infusion over 60 minutes daily is given at weeks 6, 15, 24. **The dose of cyclophosphamide is 440 mg/M^2/day x 5 days for all patients who weigh more than 30 kilograms.**

MESNA 3 mg/kg/dose x 4 doses in 10 ml IV over 15 minutes x 5 days, given after cyclophosphamide, at weeks 6, 15 and 24. **The dose of MESNA should be 90 mg/M^2/dose x 4 doses x 5 days for all patients who weigh more than** 30 kilograms.

G-CSF, 5 micrograms/kg/day subcutaneously 24 hours after the last dose of chemotherapy and given until ANC ≥10,000 and past the nadir for myelosuppression or a minimum of 1 week.

RADIATION THERAPY GUIDELINES: All patients will receive radiation therapy. See protocol section 6.224, Revised 6/96.

Criteria for Modification of Therapy: See protocol section 6.6.

Toxicity Criteria and Codes: See protocol Appendix III.

Adverse Drug Reaction or Death On Study: See protocol section 7.22.

Examinations After Completion of Thrapy: See protocol section 5.72.

Off Treatment Procedures: See protocol section 8.0.

STAGES I-IV/CLEAR CELL SARCOMA OF KIDNEY; STAGES II-IV/DIFFUSE ANAPLASIA

ROADMAP - REGIMEN I

Patient name: _____ NWTSG #_____

Revised Form? _____ 0=No 1=Yes Investigator: _____

Treatment Start Date: _____/_____/_____ Institution: _____
mm dd yy

Date Last Contact: _____/_____/_____
mm dd yy

At end of week 3 and within two weeks after off treatment, complete form and mail one copy to the DSC.

Ht._____cm. Wt.*_____kg. M^2_____

Year: _____

Week/Date Therapy: Record Dosages (mg)								**HX/PE** Wt/BP	Lab/Imaging Studies
0/_____	_____ DOX				XRT			X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, CHEST CT, ABD CT, ABD U/S, MUGA/ECHO, BONE SCAN#, SKELETAL SURVEY#, MRI OF BRAIN#, BMA#, BM BX#
1/_____		_____ VCR							CBC W/DIFF
2/_____		_____ VCR							CBC W/DIFF
3/_____			_____ CTX	_____ E				X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A,
4/_____		_____ VCR							CBC W/DIFF
5/_____		_____ VCR							CBC W/DIFF
6/_____	_____ DOX	_____ VCR	_____ CTX*					X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A,
7/_____		_____ VCR							CBC W/DIFF
8/_____		_____ VCR							CBC W/DIFF
9/_____			_____ CTX	_____ E				X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, ABD U/S
10/_____		_____ VCR							CBC W/DIFF
11/_____		_____ VCR							CBC W/DIFF
12/_____	_____ DOX	_____ VCR*	_____ CTX*					X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A,
13/_____		_____ VCR*							CBC W/DIFF
14/_____									CBC W/DIFF
15/_____			_____ CTX	_____ E				X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A,
16/_____									CBC W/DIFF
17/_____									CBC W/DIFF
18/_____	_____ DOX	_____ VCR*	_____ CTX*					X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A,
19/_____									CBC W/DIFF
20/_____									CBC W/DIFF
21/_____			_____ CTX	_____ E				X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, ABD U/S, MUGA/ECHO
22/_____									CBC W/DIFF
23/_____									CBC W/DIFF
24/_____	_____ DOX	_____ VCR*	_____ CTX*					X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A,
25/_____									CBC W/DIFF
26/_____									CBC W/DIFF
27/_____								X	CBC W/DIFF, SGPT, ALK PHOS, T.BILI, BUN/CREAT, U/A, CXR, ABD CT, ABD U/S, BONE SCAN#, SKELETAL SURVEY#, MRI OF BRAIN#, BMA#, BM BX#

* See Chemotherapy Guidelines on page 2 for dosage modifications.
# Only for Clear Cell Sarcoma of the kidney

Code up to six (6) most important complications occurring during the above dates (i.e., grade 3 or 4, or any event causing change of therapy). Code blood counts if they cause delay, decrease, or change of therapy. See Appendix III for toxicity criteria and codes.

RECORD TOXICITY TYPE, SEVERITY GRADE, AND DATES

Type			Grade	Onset	Max	Clear	Comments:
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	
				/ /	/ /	/ /	

If patient has delay or interruption of therapy for psychosocial or environmental reasons, use code 999.

Call coordinator for any grade 4 CNS toxicity, any fatal toxicity, and/or if patient goes off treatment for any reason other than relapse. (see Section 8.0 for studies to be obtained at relapse.)

Code only data occurring weeks 1-27. **OBTAIN OTHER STUDIES AS NEEDED FOR GOOD PATIENT CARE.**

ROADMAP FOR REGIMEN I, cont'd.

Eligibility Requirements: See protocol section 3.0.

Specimens for Histologic Review: See protocol section 5.111 and 5.14.

Specimens for Biologic Studies: See protocol section 5.112.

Staging Criteria: See protocol section 5.2.

Pre-treatment Evaluation: See protocol section 5.6.

CHEMOTHERAPY GUIDELINES **(Note: The day of nephrectomy will be considered day 0;** the first dose of chemotherapy will be measured in days from that starting point.) No dose of doxorubicin or carboplatin, and no course of cyclophosphamide or etoposide should be initiated if the absolute neutrophil count is <1,000/mm^3 or the platelet count is <100,000/mm^3.

Babies ≤11 months of age should receive ONE-HALF of the recommended dose of all chemotherapeutic agents, as calculated on the basis of body weight. Full doses of chemotherapeutic agents should be administered to these patients when the child is ≥12 months of age.

STAGES I-IV/CLEAR CELL SARCOMA OF THE KIDNEY (CCSK) OR STAGES II-IV/DIFFUSE ANAPLASIA: Nephrectomy, abdominal irradiation using 1080 cGy for all patients, whole lung irradiation for patients with pulmonary metastases, chemotherapy with vincristine, doxorubicin, etoposide, cyclophosphamide and MESNA using **Regimen I** (see below). Trimethoprim/sulfamethoxazole (TMX) prophylaxis - 2.5 mg/kg bid on three consecutive days per week from the start of therapy, continuing for six months after chemotherapy is complete.

Vincristine (VCR) 0.05 mg/kg IV push (maximum dose - 2mg.), beginning day 7 post-nephrectomy (week 1) if peristalsis has been established, then at weeks 2, 4, 5, 6, 7, 8, 10 and 11. **The dose of VCR is 1.5 mg/M^2 IV push for all patients who weigh more than 30 kg., but no single dose should exceed 2.0 mg.** VCR 0.067 mg/kg IV push (maximum dose - 2 mg) at week 13, and with DOX at weeks 12, 18 and 24. **The dose of VCR is 2.0 mg/M^2 IV push for all patients who weigh more than 30 kg., but no single dose should exceed 2.0 mg.**

SEE ADMINISTRATION SCHEDULE OF CTX, MESNA AND DOX: 6.17141 OF PROTOCOL.

Doxorubicin (DOX) 1.5 mg/kg IV, is given at weeks 0, 6, 12, 18 and 24. **The dose of DOX administered at week 6 should be decreased by 50% (0.75 mg/kg) if whole lung or whole abdomen radiation therapy has been given. The dose of DOX at weeks 0, 6, 12, 18 and 24 is 45 mg/M^2 IV push for all patients who weigh more than 30 kg. The dose at week 6 should be decreased by 50% (22.5 mg/M^2) if whole lung or whole abdomen radiation therapy has been given.**

Cyclophosphamide (CTX) 14.7mg/kg/day x 3 days in 200cc/M^2 of D5/ ½ NS as an IV infusion over 60 minutes daily is given at weeks 6, 12, 18 and 24. **The dose of CTX is 440 mg/M^2/day x 3 days for all patients who weigh more than 30 kg.**

MESNA 3 mg/kg/dose x 4 doses in 10 mg IV over 15 minute x 3 days, given after CTX, at weeks 6, 12, 18 and 24. **The dose of MESNA should be 90 mg/M^2/dose x 4 doses x 3 days for all patients who weigh more than 30 kg.**

SEE ADMINISTRATION SCHEDULE OF CTX, MESNA AND ETOPOSIDE: 6.17171 OF PROTOCOL.

Cyclophosphamide (CTX) 14.7 mg/kg/day x 5 days in 200 cc/M_2 of D5/½ NS as an IV infusion over 60 minutes daily is given at weeks 3, 9, 15 and 21. **The dose of CTX is 440 mg/M^2/day x 5 days for all patients who weigh more than 30 kg.**

MESNA 3 mg/kg/dose x 4 doses in 10 mg IV over 15 minutes x 5 days, given after CTX, at weeks 3, 9, 15 and 21. **The dose of MESNA should be 90 mg/M^2/dose x 4 doses x 5 days for all patients who weigh more than 30 kg.**

G-CSF, 5 micrograms/kg/day subcutaneously beginning 24 hours after the last dose of chemotherapy and given until ANC ≥10,000 and past the nadir for myelosuppression or a minimum of 1 week.

Etoposide (E) (VP-16), 3.3 mg/kg/day x 5 days in 200 cc/M^2 of D5/½NS as an IV infusion over 60 minutes daily is given at weeks 3, 9, 15, and 21. **The dose of etoposide is 100 mg/M^2/day x 5 days for all patients who weigh more than 30 kg.**

Criteria for Modification of Therapy: See protocol section 6.6.

Toxicity Criteria and Codes: See protocol Appendix III.

Adverse Drug Reaction or Death On Study: See protocol section 7.22.

Examinations After Completion Therapy: See protocol section 5.72.

Off Treatment Procedures: See protocol section 8.0.