Chemo/XRT/Surgery Working Group:

Current MRAF (circa 1990)

Abstracts chemotherapy, surgery, some radiation detail

Areas to address:

- process of registration
- chemotherapy content
- cumulative dose agents
- radiation process
- surgery process
- data submission
- data processing / editing
- quality control

University of Minnesota

CCRF Epidemiology Research Unit Division of Epidemiology/Clinical Research Department of Pediatrics Suite 300 1300 S. Second St. Minneapolis. MN 55454

DICAL CENTER, HOUSTON CHILDREN'S HOSPITAL, DENVER CHILDREN'S HOSPITAL OF DREN'S HOSPITAL ANGELES CHILDREN'S HOSPITAL & MEDICAL CENTER, SEATTLE PARTICLE OF THE HOLDREN'S MEDICAL CENTER SEATTLE PARTICLE OF THE HOLDREN'S MEDICAL CENTER OF THE HOLDREN'S MEDICAL CENTER OF THE HOSPITAL SLOAN-RETTERING CANCER CENTER, NEW YORK MINNEAPOLIS CHILDREN'S MOSTIC CHILDREN'S HOSPITAL, INDIANAPOLIS STREAM OF THE HOSPITAL SLOAN-RETTERING CANCER CENTER, NEW YORK MINNEAPOLIS CHILDREN'S SEEARCH SELVEY YOR SELVEY OF SELVEY OF SELVEY OF MEDICINE, SAN FRANCISCO ABAMA, BIRMINGHAM UNIVERSITY OF MINNESOTA, MINNEAPOLIS UT-SOUTHWESTERN DALLAS ROSWELL PARK, BUFFALO HOSPITAL FOR SICK CHILDREN, TORONTO DALLAS ROSWELL PARK, BUFFALO HOSPITAL FOR SICK CHILDREN, TORONTO

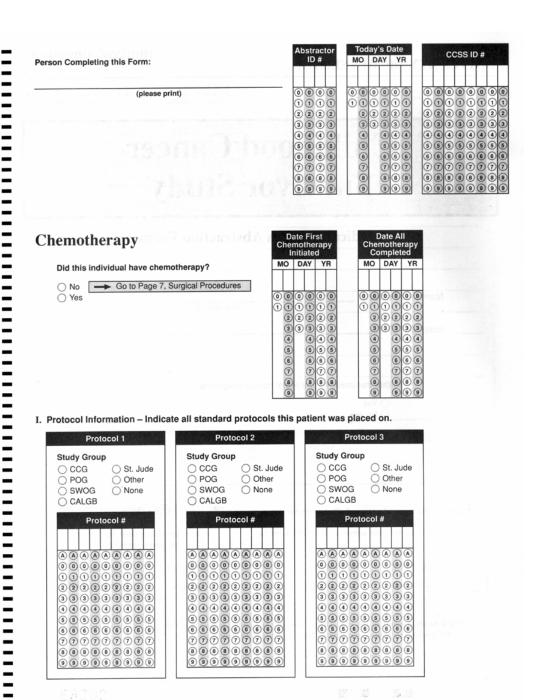
Medical Records Abstraction Form

	(Please print)	
Hospital ID #:		
Is this treatment for the initial cancer	diagnosis?	
○ Yes ○ No —		
- If no, number of new tumor (e.	a second third malians	anou)
second four third fifth		
Use the No. 2 pencil enclosed (Please do not use pen).	USE NO. 2	PENCIL ONLY
Completely darken your answers, that is, fill in the full circle.		es must stay within s provided.
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Initial Patient Registration Data

- Diagnostic Data Originally Collected:
 - ICDO Code (currently ICDO-2)
 - Diagnosis (written field)
 - Metastatic (yes/no)
 - Site of primary tumor (text field)
 - Date of Diagnosis
- Considerations:
 - Next generation will be on-line entry: immediate feedback for "out of range" entries
 - Improve site specificity, stage, include laterality
 - Limit acceptable ICDO codes (challenge leukemia NOS)



- 2 -

Page 2:

Chemotherapy: yes/no

Protocol information

Recommendation:

- record completed for each treatment plan (this means a new one for a relapse or new cancer)
- start/stop dates reflect planned therapy
- continue to collect protocol identification (but probably only need one for each treatment plan)

II. Chemotherapy Information (exposure)

Please indicate chemotherapies use	ed and routes	given.	disco due to	nis drug ntinued toxicity?	Route of Administration (Mark all that apply)			
	No	Yes	No	Yes	IV/IM	Sub-Q	Oral	
Actinomycin-D	0	0	0	0	0	0	0	
Adenine Arabinoside (Ara A)	0	0	0	0	0	0	0	
m-AMSA (Amascrine)	0	0	0	0	0	0	0	
AZQ (Diaziquone)	0	0	0	0	0	0	0	865
5-Azacytidine	0	0	0	0	0	0	0	
BCNU (Carmustine)	0	0	0	0	0	Ö	0	Thirty.
Bleomycin	0	0	0	0	0	0	0	
Busulfan	0	0	0	0	0	O	Õ	1929
Carboplatin	0	0	0	0	0	0	O	
CCNU (Lomustine)	Ô	0	0	0	0	Ö	O	
Chlorambucil	0	0	0	0	0	O	0	-
Cis-Platinum	Ö	Õ	Ŏ	Ŏ	Ŏ	Ö	Ŏ	
Cyclocytidine Hydrochloride	0	0	O	Ŏ	O	Ŏ	Õ	2001000000
Cyclophosphamide (Cytoxan)	0	0	O	Ó	Õ	Ŏ	Õ	
Cytosine Arabinoside (Ara-C)	Ö	O	0	Ŏ	Ö	Ö	0	
Daunorubicin (Daunomycin)	Ö	O	0	Ö	0	O	0	
Deoxycoformycin	Ö	Õ	0	ŏ	Ŏ	Ö	0	65,71001.0
Dexamethasone	Ŏ	Õ	0	Ö	0	Ö	Õ	
Doxorubicin (Adriamycin)	0	0	0	Ö	Ŏ	0	0	in is near
DTIC DOXONOSCIT (Adriamycin)	Ö	Õ	0	Ŏ	Ö	Ö	Õ	
5-FU (5 Fluorouracil)	0	0	0	Ö	0	0	0	CONTRACTOR OF
Fludarabine phosphate	0	0	0	Ö	Ö	Ö	0	
Homoharringtonine	0	0	0	0	0	0	0	
Hydroxyurea (Hydrea)		0	O	Ö	O	Ö	Ö	
Idarubicin	0	0	0	Ö	0	0	O	
	0	0	0	Õ	0			
Ifosfamide	0	0	0	0		0	0	
L-asparaginase		0	0	0	0	0	0	(150.0400)
Melphalan						0		
6-Mercaptopurine (6 MP)	0	0	0	0	0	0	0	1000000000
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Mithramycin	0	0	0	0	0	0	0	
Myeleran	0	0	0	0	0	0	0	
Nitrogen Mustard	0	0	0	0	0	0	0	70.50
Prednisone	0	0	0	0	0	0	0	(
Procarbazine	0	0	0	0	0	0	0	
Retinoic Acid	0	0	0	0	0	0	0	(
6-Thioguanine (6 TG)	0	0	0	0	0	0	0	- (
ThioTepa	0	0	0	0	0	0	0	(
Vinblastine (Velban)	0	0	0	0	0	0	0	(
Vincristine	0	0	0	0	0	0	0	(
VM-26 (Teniposide)	0	0	0	0	0	0	0	(
VP-16 (Etoposide)	0	0	0	0	0	0	0	
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Page 3: Chemo Exposures

Recommendations:

Add: Mitoxantrone, ARA-G, Topotecan, Temozolomide, Irinotecan, Gemcitabine, Gleevec, Fenretinide, Vinorelbine, Taxol, Taxotere,

Immunotherapy Section
Monoclonals: Mylotarg, Rituxan:
IL2, IFN, ATG, Campath, Other

Other agents: CSA, MMF, Tacrolimus, Sirolumus, Zinecard, Mesna, Growth factors (GCSF, GMCSF, Erythropoietin) II. Chemotherapy Information (exposure)

Please indicate chemotherapies use	d and routes	given.	disco	nis drug ntinued toxicity?		Route of Ad (Mark all t	ministratior hat apply)	
	No	Yes	No	Yes	IV/IM	Sub-Q	Oral	
Actinomycin-D	0	0	0	0	0	0	0	
Adenine Arabinoside (Ara A)	0	0	0	0	0	0	0	(
m-AMSA (Amascrine)	0	0	0	0	0	0	0	(
AZQ (Diaziquone)	0	0	0	0	0	0	0	(
5-Azacytidine	0	0	0	0	0	0	0	. (
BCNU (Carmustine)	0	0	0	0	0	0	0	(
Bleomycin	. 0	0	0	0	0	0	0	(
Busulfan	0	0	0	0	0	0	0	(
Carboplatin	0	0	0	0	0	0	0	(
CCNU (Lomustine)	0	0	0	0	0	0	0	(
Chlorambucil	0	0	0	0	0	0	0	(
Cis-Platinum	Ô	0	0	0	0	0	Ŏ	(
Cyclocytidine Hydrochloride	0	0	0	0	0	0	0	(
Cyclophosphamide (Cytoxan)	0	O	0	Ŏ	O	Ŏ	Õ	(
Cytosine Arabinoside (Ara-C)	0	O	Ŏ	Ŏ	Ŏ	O	Ö	(
Daunorubicin (Daunomycin)	0	0	0	Ŏ	Ö	Ö	0	(
Deoxycoformycin	O	O	0	Ŏ	Ŏ	Ŏ	Õ	(
Dexamethasone	Ö	O	0	Ö	O	O	0	(
Doxorubicin (Adriamycin)	0	Ŏ	0	Ŏ	Ŏ	Õ	Õ	(
DTIC	Ö	Õ	O	Ŏ	Õ	Õ	Õ	(
5-FU (5 Fluorouracil)	0	O	0	Ŏ	Ŏ	Ŏ	O	(
Fludarabine phosphate	Ŏ	0	0	Ŏ	O	Ŏ	Ö	(
Homoharringtonine	0	O	O	O	Ö	Ö	O	(
Hydroxyurea (Hydrea)	Ŏ	Ö	Ö	Ö	O	Ö	Ö	(
Idarubicin	0	0	0	O	O	Ö	Ö	(
Ifosfamide	Ŏ	0	0	Ó	0	0	0	(
L-asparaginase	0	0	0	O	0	0	0	(
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6-Mercaptopurine (6 MP)	O	0	0	Ö	0	Ö	0	(
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Procarbazine	0	0	Ô	0	0	0	0	
Retinoic Acid	0	0	0	-				(
6-Thioguanine (6 TG)	0	0	0	0	0	0	0	(
ThioTepa (Valley)			_	-			0	(
Vinblastine (Velban)	- 0	0	0	0	0	0	0	(
Vincristine	0	0	0	0	0		0	(
VM-26 (Teniposide)	0	0	0	0	0	0	0	(
VP-16 (Etoposide)	0	0	0	0	0	0	0	(
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D 1 2 3 4 5 6 7 6 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 8 6 7 8 9

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Page 3: Chemo Exposures

Recommendations:

Drop: ARA-A, Amascrine, AZQ, Cyclocytidine, Deoxycoformycin, Homoharringtonine, Myeleran, Mithramycin

Discontinued due to toxicity

III. Specific Agents

Total dose abstracted

 Total dose, some estimated

O Incomplete or

No dose data

Partial dose

Codes for Specific Agents:

01 Actinomycin-D	08 CCNU (Lomustine)	15 Doxorubicin (Adriamycin)	22 Myeleran
02 BCNU (Carmustine)	09 Cyclophosphamide (Cytoxan) - Oral	16 Idarubicin	23 Nitrogen Mustard
03 Bleomycin	10 Cyclophosphamide (Cytoxan) - IV	17 Ifosfamide	24 Procarbazine
04 Busulfan	11 Cytosine Arabinoside (Ara-C) - IV/IM	18 Melphalan	25 Thiotepa
05 Carboplatin	12 Cytosine Arabinoside (Ara-C) - IT	19 Methotrexate - IV	26 VP 16 (Etoposide) - Oral
06 Chlorambucil	13 Cytosine Arabinoside (Ara-C) - Sub Q	20 Methotrexate - IM	27 VP 16 (Etoposide) - IV
07 Cis-platinum	14 Daunorubicin (Daunomycin)	21 Methotrexate - IT	28 VM 26 (Teniposide)

For the agents listed above, please supply the following information

		Date		23.00		14.3			Cumul		Body	
1.	Drug #	MO	DAY	d YR	MO	DAY			Total I		Surface Area	Weight (kg)
Specify: Total dose abstracted Total dose, some estimated Incomplete or Partial dose No dose data (enter 99999)	0123466789	0 0 1 2 3 4 6 6 7 8 9	①① ②② ③③ ④ ⑤	0103466789	0 0 1 2 3 4 6 6 7 8 9		2 2 3 3 4 4 5 5 6 6 7 7 8 8	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2 2 2 3 3 3 9 4 4 5 5 5 5 6 6 7 7 7 7 8 8 8	Indicate Dosage µg mg gm units	0 · 0 0 1 · 11 2 · 2 2 3 · 3 2 4 · 4 4 6 · 6 6 7 · 7 7 8 · 8 6 9 · 9 0	00000 11100 2220 3330 4440 6660 6600 7770 8880 9990
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3.	Drug #	Date				ast Do			Cumul Total I		Body Surface Area	Weight (kg

Indicate Dosage

O mg

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Pages 4-6: Chemotherapy Cumulative Doses

Recommendations:

- Drop: myeleran, oral
 Cytoxan, all cytarabrine, IM methotrexate
- •Add: Mitoxantrone, Epirubicin, Doxil, (anthracycline); Vincristine (late neuropathy); oral ?Temodar (alkylating agent), ?Compound 506

III. Specific Agents

Total dose

Incomplete or Partial dose

Codes for Specific Agents:

01 Actinomycin-D	08 CCNU (Lomustine)	15 Doxorubicin (Adriamycin)	22 Myeleran
02 BCNU (Carmustine)	09 Cyclophosphamide (Cytoxan) - Oral	16 Idarubicin	23 Nitrogen Mustard
03 Bleomycin	10 Cyclophosphamide (Cytoxan) - IV	17 Ifosfamide	24 Procarbazine
04 Busulfan	11 Cytosine Arabinoside (Ara-C) - IV/IM	18 Melphalan	25 Thiotepa
05 Carboplatin	12 Cytosine Arabinoside (Ara-C) - IT	19 Methotrexate - IV	26 VP 16 (Etoposide) - Oral
06 Chlorambucil	13 Cytosine Arabinoside (Ara-C) - Sub Q	20 Methotrexate - IM	27 VP 16 (Etoposide) - IV
07 Cis-platinum	14 Daunorubicin (Daunomycin)	21 Methotrexate - IT	28 VM 26 (Teniposide)

For the agents listed above, please supply the following information

		Date						0		Body	
1.	Drug #	MO	Starte	d YR	MO	DAY	se YR	Cumul Total I		Surface Area	Weight (kg
Specify: Total dose abstracted Total dose, some estimated Incomplete or Partial dose No dose data (enter 99999)	0 1 2 3 3 4 4 6 6 6 7 7 8 8 9		3 3 4 5 6 7 8 8	1 1 2 2 3 3 4 4 5 6 6 7 7 8 8	0 0 1 1 2 3 4 6 6 7 8 9	0 1 2 3 4 5 6 7 8 9	11	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Indicate Dosage µg mg gm units	0 · 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0000 0100 2200 3330 4440 6860 6860 9890
2.	Drug #	Date	Starte	d YR	MO	DAY	se YR	Cumul Total I		Body Surface Area	Weight (kg
Specify: Total dose abstracted Total dose, some estimated Incomplete or Partial dose No dose data (enter 99999)	0 0 1 1 2 2 3 3 4 4 6 6 6 6 7 7 8 8 9 9	0 1 2 3 4 6 6 7 8 9	2 2 3 3 3 4 5 6 7 8 8	1 1 2 2 3 3 4 4 5 5 6 6 7 7 8 8	0 0 0 1 1 2 3 4 6 6 7 8 9	(5) (6) (7) (8)	1 1 2 2 3 3	0 0 0 0 0 1 1 1 1 1 2 2 2 2 2 3 3 3 3 3 4 4 4 4 6 6 6 6 6 6 6 6 7 7 7 7 7 8 8 8 8 8 9 0 0 0	Indicate Dosage µg mg gm units	.	00000 01100 2220 33300 4490 6500 6600 77700 88600
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	Date						Cumulative	Body	
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Pages 4-6: Chemotherapy Cumulative Doses

Most effective/accurate way to code exposure: dose or dose per meter sq?

Enter BSA at start and stop of cycle – must be consistent with earlier cohort (earlier cohort used BSA at start of treatment)

Error checks for units and doses

Surgical Procedures Did this individual undergo any surgical procedures? O No Go to Page 10, Radiation Therapy O Yes (This does not include placement of vascular access devices such as Broviac Catheters, Hickmans, Port-a-Caths, etc.) Include all biopsies identified under general anesthesia. If more than one procedure was done during a surgery, enter each procedure separately. Include ICD-9 code for each procedure performed. 1. Date of First Procedure: 2. Date of Second Procedure: Name of Name of procedure: procedure: (please take from operative report or op note) (please take from operative report or op note) 1st Procedure Code Code MO DAY YR MO DAY YR 00001111 1111 2222 2222 3333 3333 4444 4444 5 5 5 5 5 5 5 5 6666 7777 7777 8888 8888 9999 Where was this procedure performed? Where was this procedure performed? O This CCSS institution This CCSS institution Other institution: specify 3. Date of Third Procedure: 4. Date of Fourth Procedure: Name of Name of procedure: procedure: (please take from operative report or op note) (please take from operative report or op note) ICD-9 4th Procedure Code MO DAY YR Code MO DAY YR 00000000 000000 000 111111 1111 1111111 2222 2222 3 3 3 3 3333 4 4 4 4

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O This CCSS institution

Other institution: specify

Where was this procedure performed?

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This CCSS institution

Where was this procedure performed?

Pages 7-9: Surgical **Procedures**

Recommendations:

- provide location and name of outside facilities
- ?create list of most common surgeries?
- Plan to poll all working group chairs for hypotheses related to surgical procedures
- Possible restriction of surgical abstractions / ?central abstraction

Radiation Therapy

Did Male	individual	ragaine	radiation	thorany?

○ No	→ Go	to Page	12, Co	mments	Section
O Yes	7				

Please complete a copy of the External Beam or Brachytherapy Data Checklist.

Return this checklist and copied records to the Coordinating Center.

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Facility:	
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Radiation Therapy
Facility: ______

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Oncologist:

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Facility:	
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Pages 10-11: Radiation Therapy

Recommendations:

- copy photograph of patient with fields marked if available
- provide location data and name of radiation facility
- scan records at institution prior to sending to MD Anderson (?)

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Pages 12: Comments Section Other considerations?



Chemo/XRT/Surg Timeline

- Establish <u>working</u> group
- December 2005
 - Final decisions regarding content of MRAF and Registration Screens
- March 2006
 - MRAF data entry system complete and tested
- April 2006
 - Data management training session