

PEDIATRIC HEART TRANSPLANT STUDY

FORM 05: 2010: Rejection (PG 1 of 2)

To be filled out post-transplant

ID#	P								
		Institutional Code	Sequential Patient Number	Patient Initials	Tran #				

1. Weight at time of rejection: _____ lb kg

2. Baseline immunosuppressive therapy at time of rejection:

- | | |
|---|---|
| <input type="checkbox"/> Prednisone | <input type="checkbox"/> Cytoxan |
| <input type="checkbox"/> Azathioprine (Imuran) | <input type="checkbox"/> Plasmapheresis: Frequency: _____ |
| <input type="checkbox"/> Cyclosporine: | <input type="checkbox"/> Rituximab |
| <input type="checkbox"/> Sandimmune <input type="checkbox"/> Neoral <input type="checkbox"/> Gengraf <input type="checkbox"/> Other | <input type="checkbox"/> Immune globulin |
| <input type="checkbox"/> Tacrolimus (Prograf, FK506) | <input type="checkbox"/> Other, specify: _____ |
| <input type="checkbox"/> Methotrexate | <input type="checkbox"/> Other, specify: _____ |
| <input type="checkbox"/> Mycophenolate (Cellcept, Myfortic) | <input type="checkbox"/> Other, specify: _____ |
| <input type="checkbox"/> Sirolimus (Rapamycin) | <input type="checkbox"/> Other, specify: _____ |

3. Biopsy prior to date of rejection diagnosis: Not Done

Date: ____ ____ ____ ACR ____ AMR ____

4. Rejection: Start with newly diagnosed rejection by biopsy (convert to ISHLT score) or other criteria leading to bolus immunotherapy. List all follow-up biopsies or changes in therapy. The last entry should be first biopsy or echo not prompting additional therapy.

THERAPY CODES: Please list therapies using the following codes:

- | | | |
|---------------------------------|-------------------|----------------------|
| 1 = Steroids, IV | 10 = Other: _____ | 16 = Rituximab |
| 2 = Steroids, Oral | 11 = Other: _____ | 17 = Plasmapheresis |
| 4 = ATG | 12 = Other: _____ | 18 = Photopheresis |
| 5 = ALG | 13 = Other: _____ | 19 = Cytoxan |
| 6 = Steroid taper | 14 = Other: _____ | 20 = Immune globulin |
| 7 = Methotrexate | 15 = Other: _____ | |
| 8 = ATS | | |
| 9 = Tacrolimus (Prograf, FK506) | | |

***N = First biopsy without rejection requiring additional treatment**

Biopsy A. Date of Diagnosis, Start of New Therapy, Change in Therapy, & all Biopsies until no bolus therapy added.	Basis for Dx: All that apply			Biopsy Score		Indication for Biopsy (check one only)				Rejection Therapy: (see choice codes above)	Total Days of Therapy:	Hemo- dynamic Compromise?						
	Echo	Clinical	Biopsy	ACR	AMR*	Routine protocol	Obj. Evid. Graft Dys.	Symtoms	Research									
<table border="1" style="width: 100%; text-align: center;"> <tr> <td style="width: 33%;"> </td> <td style="width: 33%;"> </td> <td style="width: 33%;"> </td> </tr> <tr> <td>(MO DAY YR)</td> <td></td> <td></td> </tr> </table>				(MO DAY YR)			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. _____	_____	<input type="checkbox"/> None
(MO DAY YR)																		
										2. _____	_____	<input type="checkbox"/> Mild						
										3. _____	_____	<input type="checkbox"/> Inotropic support used						
										4. _____	_____							
										5. _____	_____							
										6. _____	_____							

Special studies for antibody mediated rejection (AMR): (check all that apply)

- Are there biopsy features consistent with AMR? Yes No
- If Yes: Yes No Immunofluorescence studies? Positive Negative
- Yes No C4D staining? Positive Negative

PRINT IN BLACK INK ONLY. USE THIS FORM FOR ALL PATIENTS OR EVENTS AFTER JANUARY 1, 2010

PEDIATRIC HEART TRANSPLANT STUDY

FORM 05: 2010: Rejection (PG 2 of 2)

To be filled out post-transplant

ID# P	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
P	Institutional Code	Sequential Patient Number	Patient Initials	Tran #

See page 1 for therapy codes

Biopsy B.

Date of Diagnosis, Start of New Therapy, Change in Therapy, & all Biopsies until no bolus therapy added.

<input type="text"/>	<input type="text"/>	<input type="text"/>
(MO	DAY	YR)

Basis for Dx: All that apply			Biopsy Score		Indication for Biopsy (check one only)				Rejection Therapy: (see choice codes above)	Total Days of Therapy:	Hemo-dynamic Compromise?
Echo	Clinical	Biopsy	ACR	AMR*	Routine protocol	Obj. Evid. Graft Dys.	Symptoms	Research			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	_____	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Inotropic support used
			* if AMR then please complete special studies for antibody mediated rejection								

Special studies for antibody mediated rejection (AMR): (check all that apply)

Are there biopsy features consistent with AMR? Yes No
 If Yes: Yes No Immunofluorescence studies? Positive Negative
 Yes No C4D staining? Positive Negative

Biopsy C.

Date of Diagnosis, Start of New Therapy, Change in Therapy, & all Biopsies until no bolus therapy added.

<input type="text"/>	<input type="text"/>	<input type="text"/>
(MO	DAY	YR)

Basis for Dx: All that apply			Biopsy Score		Indication for Biopsy (check one only)				Rejection Therapy: (see choice codes above)	Total Days of Therapy:	Hemo-dynamic Compromise?
Echo	Clinical	Biopsy	ACR	AMR*	Routine protocol	Obj. Evid. Graft Dys.	Symptoms	Research			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	_____	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Inotropic support used
			* if AMR then please complete special studies for antibody mediated rejection								

Special studies for antibody mediated rejection (AMR): (check all that apply)

Are there biopsy features consistent with AMR? Yes No
 If Yes: Yes No Immunofluorescence studies? Positive Negative
 Yes No C4D staining? Positive Negative

Biopsy D.

Date of Diagnosis, Start of New Therapy, Change in Therapy, & all Biopsies until no bolus therapy added.

<input type="text"/>	<input type="text"/>	<input type="text"/>
(MO	DAY	YR)

Basis for Dx: All that apply			Biopsy Score		Indication for Biopsy (check one only)				Rejection Therapy: (see choice codes above)	Total Days of Therapy:	Hemo-dynamic Compromise?
Echo	Clinical	Biopsy	ACR	AMR*	Routine protocol	Obj. Evid. Graft Dys.	Symptoms	Research			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____	_____	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Inotropic support used
			* if AMR then please complete special studies for antibody mediated rejection								

Special studies for antibody mediated rejection (AMR): (check all that apply)

Are there biopsy features consistent with AMR? Yes No
 If Yes: Yes No Immunofluorescence studies? Positive Negative
 Yes No C4D staining? Positive Negative

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Person completing this form: _____ Date original form mailed (do not send copy) _____