UT SOUTHWESTERN MEDICAL CENTER eResearch eIRB/eCOI

Date: Monday, June 10, 2013 12:14:37 PM

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View: 1.0 Modification Type

1.0 Modification Type

* **1.1 Check all that apply:**

- [x] **Study Personnel**
- [ ] Principal Investigator
- [ ] Co-Investigator
- [x] **Protocol**
- [ ] Investigator Brochure
- [ ] Consent Form
- [ ] HIPAA Authorization
- [ ] HIPAA Waiver of Authorization
- [ ] Target Enrollment
- [ ] Recruitment Materials
- [ ] Other

1.2 If this modification corresponds with a modification requested by the study sponsor, please provide the modification name/number, protocol version or other identifier(s):

View: 9.0 Protocol Changes

9.0 Protocol Changes

* **9.1 Please describe the protocol change(s):**
Addendum to study Protocol

We like to evaluate the infectious etiologies like Epstein-Barr virus (EBV), Cytomegalovirus status of these patients which also could be responsible for rejection or post-transplant lymphoproliferative disease (PTLD) in patients after heart transplants. In addition to study of the rejection episodes, we would like to exclude if allograft rejection due to infections. We also would like to collect EBV serological status before transplant and EBV level by PCR after transplant. We would like to compare if EBV viral load increase at the time of rejection. This study also will review patients with high EBV levels and impact of reduced immunosuppresive therapy as a part of treatment of lymphoproliferative disorder in these patients. These data are already available and no new data will be collected for the study.

Additionally, inorder to diagnose whether the rejection episodes due to HLA antibodies are hemodynamically significant, we would like to evaluate patients chemistries (Liver and kidney function). Kidney function is better assessed by glomerular filtration rate (GFR). All these labs are routinely done in these patients and are available for retrospective review. All transplant patients have routinely 24hr urine collection for creatinine level and serum creatinine level as a part of their evlauation to manage their kidney function. We are requesting to add GFR to data collection in these patients to understand the effect of allograft rejection on kidney function. This also helps to understand chronic effect of immunosuppressive therapy like Tacrolimus and Cyclosporine on their kidney function. GFR will be calculated based on body surface area and 24 hr creatinine in urine, serum creatinine.Thi is already done and results are available for each patient.

All the above additional data collection will be from Children's Medical Center EPIC electronic medical record revie. All these are retrospective data review. None of these will be done as a part of the study. We are adding these parameters to the previous data collection to better analyse these patients, their allograft function, PTLD incidence and outcome in relation to immunosuppresssive therapy and rejections.

We have added a template for data collection for the study.

9.2 Have radiologic exams been added to the protocol or has there been a change in the number or type of radiologic exam?

Yes **No**

9.3 Please upload the red-lined version of the protocol:

Name	Version
There are no items to display	

* **9.4 Has the risk/benefit ratio of the research changed?**

Yes **No**

9.4.1 If yes, please describe:

* **9.5 Do any of the protocol changes affect the consent form?**

Yes **No**

9.6 Please follow the link to upload a clean copy of the revised protocol in the parent study SmartForm:

Protocol Change

View: 11.0 Study Personnel

11.0 Study Personnel

Current Research Coordinator:
DEBORAH MCELROY

11.1 Primary Research Coordinator:
DEBORAH MCELROY

Current Primary Administrative Contact:

11.2 Primary Administrative Contact:

Current Other Study Personnel:

Last Name	First Name	HIPAA	GCP	HSP
Das	Bibhuti	11/28/2011	11/28/2011	11/28/2011

11.3 Other Study Personnel:

Last Name	First Name	HIPAA	GCP	HSP
Das	Bibhuti	11/28/2011	11/28/2011	11/28/2011
Crockett	Jessica	7/21/2009	7/21/2009	7/21/2009

Current Non-UTSW Study Personnel

Last Name	First Name	Middle Name	Institution
There are no items to display			

11.4 Non-affiliated Study Personnel:

Last Name	First Name	Middle Name	Institution
There are no items to display			

* **11.5 Do the study personnel changes affect the consent form?**

○ Yes ◉ **No**

View: 14.0 Summary of Changes and Next Steps

14.0 Summary of Changes and Next Steps

14.1 You indicated this modification is changing/updating the following items:

Study Personnel

Protocol

Note: If administrative or other changes are indicated, please ensure that all applicable sections have been revised/updated.

14.2 Please follow the link to edit the study:

MS1_STU 072012-061

14.3 Comments: