



LOMA LINDA UNIVERSITY

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Loma Linda University

Informed Consent

OBSERVATIONAL STUDY OF ACTIVATED CLOTTING TIMES IN HEPARINIZED PEDIATRIC HEMODIALYSIS SUBJECTS

You are invited to participate in a research study because you or your child are receiving hemodialysis therapy.

The purpose of this research study is determine the best means to dose heparin, which is used to anti-coagulate the blood. For pediatric hemodialysis subjects, we currently use a method to dose heparin, which was derived from adult studies.

Participation in this study will continue for as long as you or your child need hemodialysis or until the study has been completed in December 2009 (whichever is first).

Participation in this study involves no experimental treatment. There will be no change in you or your child current heparin prescription. Your doctor will continue to adjust you or your child heparin to achieve adequate anti-coagulation according to the standard of care. We will record the dose of heparin, some physical measurements and you or your child response to the therapy as determined by the activated coagulation test (ACT). The pediatric hemodialysis unit routinely uses ACT to determine the correct dosing of heparin.

There are no medical risks associated with participation in this study. Breach of confidentiality is the main risk associated with this study.

There are no direct benefits to you or your child as a result of participating in this study. The benefit to humanity may be a better understanding of how to effectively dose heparin in pediatric hemodialysis patients.

Participation in this study is voluntary. Your decision whether or not to participate or terminate (or to allow your child to participate or terminate) at any time will not affect your present or future medical care.

Any published document resulting from this study will not disclose your (your child's) identity without your permission. The U.S. Food and Drug Administration, the Department of Health and Human Services, and/or their designee(s) may inspect the records relating to your (your child's) participation in this study.

There is no cost to you (your child) for participating in this study.

If you wish to contact an impartial third party not associated with this study regarding any question or complaint you may have about the study, you may contact the Office of Patient Relations, Loma Linda University Medical Center, Loma Linda, CA 92354, phone (909) 558-4647 for information and assistance

Informed Consent Statement

I have read the contents of the consent form and have listened to the verbal explanation given by the investigator. My questions concerning this study have been answered to my satisfaction. This study has been explained to my child in a manner appropriate to his/her age and maturity. I hereby give voluntary consent to participate in this study (or for my child to participate in this study). Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities. I may call Peter Yorgin, MD during routine office hours at (909) 558-8242 or during non-office hours at (909) 558-4000 and ask for the Pediatric Nephrologist on call if I have additional questions or concerns.

I have been given a copy of this consent form.

For adult subjects and minors 12 years or older

Signature of subject

Date

For children less than 12 years of age

This study has been explained to my child at a level that he/she can comprehend and I give my consent for my child to participate in the study

Signature of parent or guardian

Date

Investigator

I have reviewed the contents of the California Experimental Subject's Bill of Rights and this consent form with the person signing above. I have explained potential risks and benefits of the study.

Signature of Investigator

Phone Number

Date

Inpatient studies

As the primary physician responsible for the care of the patient, I indicate having knowledge of this research participation.

Signature of subject

Date

Signature of primary physician