Principal Investigator:	Annette Rebel, MD	Date: October 13, 2014
Study Title:	Coagulation assessment with Thromboelastography and Prothrombin time / INR as indicator for coagulopathy in end stage liver disease before liver transplant	

Form E
Include in IRB Application to
Waive Requirement for Informed Consent

If you are requesting IRB approval for waiver of the requirement for the informed consent process, or alteration of some or all of the elements of informed consent (i.e. medical record review, deception research, or collection of biological specimens), complete Section 1 and Section 2 of this form and include it with your IRB application submission.

Note: The IRB does not approve waiver or alteration of the consent process for research that is subject to FDA regulations, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1

Check the appropriate item:

☒ 1) I am requesting waiver of the requirement for the informed consent process.

☐ 2) I am requesting alteration of the informed consent process.
If you checked the box for this item, describe which elements of consent will be altered, and/or omitted, and justify the alteration.

SECTION 2

The IRB may consider your request provided that **all** of the following conditions apply to your research and are appropriately justified. Explain in the space provided for each condition how it applies to your research.

a) The research involves no more than minimal risk to the subject.
This is a retrospective chart review with de- identified information. The risk presented to subjects is no more than minimal.

b) The rights and welfare of subjects will not be adversely affected.
The rights and welfare of subjects will not be adversely affected. All information will be de- identified and only written about in aggregate.

c) The research could not practicably be carried out with out the waiver or alteration.
The research could not practicably be carried out without the waiver, due to these individuals being previous patients of the UK Hospital, some of whom are anticipated to be deceased.

d) Whenever possible, the subject will be provided with additional pertinent information after they have participated in the study.
Not applicable.