Baylor College of Medicine
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MEMORANDUM

TO: RYAN WALLACE HIMES
PEDIATRICS: GASTROENTEROLOGY

FROM: BAMBI JO GRILLEY, B.S.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

DATE: June 4, 2018

RE: **H-39130 - FACTORS INFLUENCING OUTCOMES OF LIVER TRANSPLANTATION IN CHILDREN**

The IRB, through expedited procedures has approved on 5/23/2018, a consent procedure which waives the requirement to obtain informed consent/HIPAA authorization for this research, and hereby describes how both of the following are found and documented in this protocol:

Waiver of consent and HIPAA authorization has been approved for the research as described here: As this is a chart review activity encompassing the cohort of children who have been listed for liver transplantation at Texas Children's, a waiver of consent is required to practically conduct the research.

a) The research and the use or disclosure of protected health information involves no more than minimal risk (including privacy risks) to the individuals because:

The research does not involve any interventions, nor additional labs or procedures, only review of previously obtained clinical information, so the chief risk is loss of confidentiality. Through countermeasures, namely deidentification of data and restricting the storage of research data to firewalled, password-protected Texas Children's assets, we believe this risk is quite small.

1. An adequate plan exists in order to protect health information identifiers from improper use and disclosure, because:

   Once study subjects are identified, they will be assigned a numerical ID. The database will be password-protected on secure Texas Children's servers, minimizing the risk of inadvertent loss of confidentiality.

2. An adequate plan exists in order to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so), because:

   Data identifiers will be stored for five years following publication, after which any paper data will be destroyed by disposing in Texas Children's PHI disposal bins. Electronic identifiers will be destroyed by deleting the data, or by contacting Texas Children's IT department.

3. Adequate written assurances exist in order to ensure that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the

research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule, because:

We confirm that PHI will not be used or disclosed to any other person or entity except as required by law, for authorized oversight of the research, or for other research for which the use or disclosure of the PHI would be permitted under the privacy rule.

b) The informed consent waiver will not adversely affect the rights and welfare of the subjects, because:

The waiver will not adversely affect the privacy rights of the subjects because there is no more than minimal risk and reasonable safeguards have been established to mitigate the small residual risk of loss of confidentiality.

c) The research could not practicably be carried out without the waiver or alteration, and the research could not practicably be conducted without access to and use of the requested information because:

In order to capitalize on the main strength of our program, we need to include in our analyses all patients who have been listed for transplantation at our center over time, including those who were transplanted, those who recovered without the need for liver transplantation, and those who died awaiting transplant. To do otherwise may introduce very important bias into our findings.

d) Informed consent is being waived, and providing participants with additional pertinent information after participation is not appropriate, because:

The subjects will have no direct, additional benefit, from any data gleaned from this research.

The following is a brief description of the PHI and the specific subject identifiers for which the IRB has determined use or disclosure to be necessary:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)

Given the assurances provided above, this memorandum serves as documentation that the BCM IRB has approved a waiver of consent/HIPAA authorization and has determined that all requirements are met by this protocol in order to grant the waiver.