UMass Memorial Medical Center
HIPAA IRB WAIVER OF AUTHORIZATION***

Principal Investigator: Deepika Devuni
IRB Study ID #: STUDY00000016
Protocol Title: Exploring barriers within the liver transplant evaluation care pathway and evaluating downstream effects

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1. **Indicate if you are requesting a waiver of authorization to review electronic/paper medical records just to find potential subjects or to conduct the entire study**.

   We will be requesting a waiver of authorization to review medical records.

2. **The HIPAA regulation requires reasonable efforts to limit protected health information to the <u>minimum necessary</u> to accomplish the intended purpose of the use, disclosure, or request. List the PHI to be collected and its source(s).**

   This study will use the minimum amount of PHI. MRN will be collected initially when identifying patients within the electronic health record; MRN will then be replaced with a unique study ID. Date of birth will be collected from electronic health record to calculate age. We will use geographic data to determine the distance of the patient from the transplant center, however this will be non-specific and grouped into 0-25 miles, 25-50 miles, 50-75 miles, 75-100 miles, over 100 miles.

   The data range for charts to be reviewed is January 2017 through December 2021.

3. **Explain why the research could not practicably be conducted without this PHI.**

   Without MRN, patients would not be able to be identified from the electronic health record. Date of birth is needed to calculate age as we intend to only review records of individuals over the age of 18. For geographic data, all data will be non-specific, but is important as distance to a transplant center is a recognized barrier to transplant.

4. **Describe the plan to protect identifiers from improper use or disclosure. Be sure to indicate where PHI will be stored, who will have access (researchers must list <u>all</u> of the entities that might have access to the study's PHI such as IRB, sponsors, FDA, data safety monitoring boards, and any others given authority by law), and the procedure used to destroy them. (Note that identifiers must be destroyed at the earliest opportunity, unless there is a justification for retaining the identifiers or retention is required by law.)**

   The MRN will be used to identify patients and then will be replaced the study will be identified by a unique study number (study ID). A table will be developed which links the unique study number to the medical record number. The table containing the key to the coded spreadsheet will be stored in separate password-protected file on Gastroenterology A Drive. The data collection instrument will be on REDCap and stored separately from the medical record list. Identifiers will be destroyed once final data analysis has begun.

5. Explain why the research could not practicably be conducted if you had to obtain permission from the individuals to access their PHI for research purposes.

This waiver is needed because requesting permission from individuals would be impracticable given the retrospective nature of this study. We will be collected as far back as 2017 and many individuals may have moved or died in this time frame. If permission were required, we would not reach all potential participants and data would be biased, especially given the mortality in patients with liver disease. Such bias in this collection would result in un-interpretable and/or meaningless data.

By submitting this form, the PI attests the following:

a) The information listed in the waiver application is accurate and all research staff** will comply with the HIPAA regulations and the waiver criteria.
b) Protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.

REMINDER: The PI is ultimately responsible for completing the required accounting of research disclosures for any PHI released under a waiver. The relevant forms are available on the IRB website and additional information regarding these obligations is available by contacting the Office of Clinical Research, UMass Center for Clinical & Translational Science (UMCCTS), or the UMass Memorial Medical Center Privacy Officer.

**Note: Research staff is defined as ALL study personnel (including PI) that is involved in the research.

***HIPAA Regulations allow IRBs to waive the use of authorization forms if all of the criteria listed above are met.