Yale University

Human Investigation Committee
Human Subjects Committee
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New Haven CT 06520-8327

Telephone: 203-785-4688
http://www.yale.edu/hrpp

APPROVAL OF SUBMISSION VIA EXPEDITED REVIEW

February 14, 2017

Jordan Sack

Dear Jordan Sack:

On 2/14/2017, the Yale Human Investigation Committee reviewed the following submission:

Type of Review:	Initial Study
Title of Study:	Quality Improvement Project: Impact of Discharge Liver Clinic for Patients Admitted at YNHH Inpatient Hepatology Unit
Investigator:	Jordan Sack
IRB Protocol ID:	2000020354
Submission ID:	2000020354
Documents:	• Sack.HRP-503C Medical Record Protocol Template.pdf, Category: IRB Protocol;

The Yale Human Investigation Committee approved this submission following an expedited review. This approval is valid from 2/14/2017 to 2/13/2018 inclusive.

Review Comments:

This approval is for medical record review only. This approval does not authorize patient contact.

Please be advised that Yale-New Haven Hospital and Yale Medical Group have implemented a new reporting request process. Requests for medical records should be made through JDAT as described at http://medicine.yale.edu/ycci/oncore/availableservices/datarequests/datarequests.aspx.

YNHH and Yale University consider it a violation of patient privacy for research personnel to review medical records of patients who have opted out of research use of their records. All record review requests should therefore be through JDAT.

A HIPAA waiver has been approved via expedited review for [access to and] use of MRN, show/no show to appointment, age (in years), sex, race, insurance, homelessness status, marital status, primary language, nutritional status, cirrhosis etiology, history of cirrhosis complications, existing medical comorbidities, cause of the admission prior to

the discharge liver clinic, admission length of stay, labs, complications, infections, vaccinations, discharge medications, discharge liver clinic date, labs, number of medication changes, if readmitted within 30 days will record similar admission values as outlined above, number of admissions as well as labs and mortality status at 90 days and 1 year without obtaining written approval ("authorization") from the subject for the use of the data. This waiver does not authorize subject contact.

The Committee finds that informed consent can be waived for this study per federal regulation 45 CFR 46.116(d). This part of the regulations states that 1) this research involves no more than minimal risk to the subjects, 2) the waiver or alteration will not adversely affect the rights and welfare of the subjects, 3) the research could not practicably be carried out without the waiver and 4) whenever appropriate the subjects will be provided with additional pertinent information after participation.

By 12/15/2017, you are to submit documentation for a continuing review. You can request a continuing review by navigating to the active study and clicking Create Modification / CR. Alternatively, you can close the study when the study procedures and the data analysis of identifiable data are fully complete. You can submit a closure request by navigating to the active study and clicking Create Modification /CR.

If you wish to change any aspect of this study, such as the study procedures or processes, the informed consent document(s), recruitment activities, or wish to add or remove investigators or study personnel, you must submit a modification to the study. Any changes must be approved by the IRB prior to implementation.

Serious, unanticipated, and related adverse events, and unanticipated problems involving risk to subjects or others must be reported generally within 5 days of the PI becoming aware of the event (see Policy 710: Reporting Unanticipated Problems Involving Risks to Subjects or Others, including Adverse Events).

In conducting this study, you should refer to and follow the Investigator Manual (HRP-103), which can be found in the IRB Library within the IRB system.

Please keep this letter with your copy of the approved protocol documents.

Sincerely,

Human Investigation Committee