Haydel, Brandy

From: West, Allyson [allyson.west@mssm.edu]
Sent: Thursday, April 25, 2013 1:14 PM
To: Schiano, Thomas
Cc: Haydel, Brandy
Subject: Approval of Research Continuation Submission GCO #10-0412 (0002)

Institutional Review Board
Program for the Protection of Human Subjects

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APPROVAL OF RESEARCH

Date: April 25, 2013

To: **Thomas Schiano, MD (thomas.schiano@mountsinai.org)**

On **4/23/2013**, an Institutional Review Board of the Mount Sinai School of Medicine, in accordance with Mount Sinai's Federal Wide Assurances (FWA#00005656, FWA#00005651) to the Department of Health and Human Services approved the following human subject research from **5/14/2013** until **5/13/2014** inclusive:

Type of Review:	**Continuing**
Project Title:	**TREATMENT OF RECURRENT HEPATITIS C FOLLOWING LIVER TRANSPLANT**
Investigator:	**Thomas Schiano, MD**
MSSM Project #:	**HS#: 11-00700, GCO#: 10-0412(0002)(04) ME**
Funding Agency:	**Genentech**
IND or IDE (if any):	**No INDs; No IDEs**
Submission Details (if any):	**None**

Before **3/30/2014** or within 30 days prior to study close, whichever is earlier, you are to submit a completed FORM HRP-212: Continuing/Final Review Progress Report and required attachments, in order to request continuing IRB approval or study closure. If IRB continuing review approval is not granted before the expiration date of **5/13/2014**, IRB approval of this research expires on that date.

The IRB has determined that this research involves no greater than MINIMAL RISK. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45CFR.46.102; 21CFR50.3k). The IRB approved this research under **expedited review procedure category(ies) #5.** ♦ The MSSM IRB approved the request for Waiver of Authorization for use and disclosure of PHI for this project on 5/14/10. This request was reviewed and approved by expedited review procedures. This approval is based on the fact that the waiver of authorization satisfies the following criteria: 1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of: A. an adequate plan to protect the identifiers from improper use and disclosure; B. an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and C. the PI has provided adequate written assurances that the PHI will not be reused or disclosed to 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 PHI would be permitted by the Privacy Regulations. 2. The research could not practicably be conducted without the waiver; and 3. The research could not practicably be conducted without access to and use of the PHI. The PHI for which access has been determined to be necessary for this project [which are the minimum necessary] include the following: Age, MRN,Name, Clinical data, laboratory data, radiology and pathology results. ♦ The request for access to decedent PHI was approved on 5/14/2010. ♦Note: The request for waiver of informed consent for retrospective chart review was approved on 5/14/10. This research presents no more than minimal

risk to the subjects, will not adversely affect the rights and welfare of the subjects, and could not practicably be carried out without a waiver. In addition, subjects will be provided with additional pertinent information after participation if the investigator believes that this would be appropriate.

In conducting this research you are required to follow the requirements listed in the **Investigator Manual**. If stamped approved consent forms are attached, use copies of these forms to document consent. IRB approval does not constitute or imply institutional support for the conduct of this research.

cc: Study Contact: Brandy Haydel brandy.haydel@mssm.edu