



**Office of Human Subjects Research  
Institutional Review Boards**

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**Date:** July 3, 2017

**APPLICATION APPROVAL**

**Review Type:** Expedited  
**Principal Investigator:** Tinsay Woreta  
**Number:** IRB00138157  
**Title:** Estimating changes in liver fibrosis over time and in specific subgroups with transient elastography (TE) in patients with chronic viral hepatitis.  
**Committee Chair:** Susan Bassett  
**IRB Committee:** IRB-X

**Date of approval:** June 29, 2017

**Date of Expiration:** June 28, 2018

The JHM IRB approved the above-referenced Application.

IRB review included the following:

**45 CFR 46.116:** A waiver of consent was granted based on the following criteria: 1) the research involves no more than minimal risk to subjects; 2) the waiver will not adversely affect the rights and welfare of the subjects; 3) the research could not be practicably carried out without the waiver; and 4) the IRB will advise you if it is appropriate for participants to be provided with additional pertinent information after participation.

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

**Date of Approval and Expiration Date:** The approval and expiration date for this research are listed above. If the approval lapses, the research must stop and you must submit a request to the IRB to determine whether it is in the best interests of individual participants to continue with protocol-related procedures.

**Changes in Research:** All proposed changes to the research must be submitted using a Change in Research application. The changes must be approved by the JHM IRB prior to implementation, with the following exception: changes made to eliminate apparent immediate hazards to participants may be made immediately, and promptly reported to the JHM IRB.

**Continuing Review:** Continuing Review Applications should be submitted at least 6 weeks prior to the study expiration date. Failure to allow sufficient time for review may result in a lapse of approval. If the Continuing Review Application is not submitted prior to the expiration date, your study will be terminated and a New Application must be submitted to reinitiate the research.

**Unanticipated Problems:** All unanticipated problems must be submitted using a Protocol Event Report.

If this research has a commercial sponsor, the research may not start until the sponsor and JHU have signed a contract.

The JHMIRB is constituted to meet the requirements of the Privacy Rule at section 45 CFR 164.512(i)(1)(i)(B) and is authorized and qualified to serve as the Privacy Board for human subjects research applications conducted by Hopkins' faculty members. The JHM IRB reviewed your request to waive authorization the above-referenced project. The IRB determined that all specific criteria for a waiver of authorization were met, as follows:

(A) The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(1) An adequate plan to protect the identifiers from improper use and disclosure;

(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(3) Adequate written assurances that the protected health information 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 protected health information would be permitted;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) the research could not practicably be conducted without access to and use of the protected health information.

### **Study documents:**

#### **HIPAA Form 4:**

form4.doc

#### **Additional Supplemental Study Documents:**

Data Security Profile.pdf

Use of Data Agreement.pdf

Requested Variables\_Revised 6-27-17.docx

Approval E-mail from Dr. Thiemann .pdf

**Protocol:**

eformB TE Study Revised 6-27-17 Clean Version.doc

**Study Team Members:**

Po-Hung Chen

The Johns Hopkins Institutions operates under multiple Federal-Wide Assurances: The Johns Hopkins University School of Medicine - FWA00005752, The Johns Hopkins University School of Nursing - FWA00006088, The Johns Hopkins Hospital and Johns Hopkins Health Systems - FWA00006087, Johns Hopkins Bayview Medical Center - FWA00006089, Howard County General Hospital - FWA00005743, Hugo W. Moser Research Institute at Kennedy Krieger, Inc. - FWA00005719, Johns Hopkins Community Physicians - FWA00002251, Suburban Hospital and Health System - FWA00005924

**This is an official communication from the KPMAS-IRB regarding your recent submission.  
Federal regulations require that you maintain a copy of this document with your study records.**

[Federalwide Assurance #00002344 ~ OHRP IRB #00000783]

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May 15, 2017

## **APPROVAL NOTICE**

**IRB Number:** MA-17-152  
**Study Title:** Estimating changes in liver fibrosis over time and in specific subgroups with transient elastography (TE)  
**Approval Period:** 05/10/2017 thru 05/09/2018

Dear Carla V Rodriguez, Ph.D.:

It was determined that the above-referenced initial review submission was eligible for expedited review. As such, on 05/10/2017, a designated reviewer for the Kaiser Permanente of the Mid-Atlantic States Institutional Review Board (KPMAS-IRB) approved your submission under the following expedited review criteria:  
*Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).*

### **Approved Research Personnel:**

Principal Investigator: Carla V Rodriguez, Ph.D.

Other Key Study Personnel: Paul, Myriam; Rodriguez, Rubenstein, Kevin; Turner, Michelle; Watson, Eric S.

**Informed consent determination(s):** Waiver approved under 45 CFR 46.117 (c) 1 or 2/ 21 CFR 56.109 (c)1

**HIPAA determination(s):** Waiver of HIPAA Authorization for Research approved under 45 CFR 164.512 (i) (2) (ii)

**Number of Participants:** The IRB approved the request to **enroll up to 4600 research participants**. Increasing the number of participants without IRB approval of an amendment is considered a protocol deviation.

### **Please Read the Following Information Carefully:**

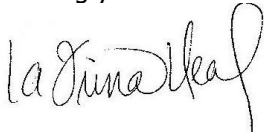
The current expiration date for this study is: 05/09/2018

**(The expiration date is the last day that a research study has IRB approval.)**

- Federal regulations require that all studies be reviewed at least annually. It is your responsibility to ensure that you apply for re-approval within one year (or the timeframe specified by your approval notice). **Please refer to the attached information sheet about your IRB approval notice.**

- If your study or IRB-approved study documents require ANY modification, you must seek IRB approval for these changes before they are implemented **except** when necessary to eliminate apparent immediate hazards to one or more subjects. If you determine that an immediate modification is critical in order to eliminate hazards to one or more subjects, you must notify the IRB within five business days of having carried out such changes to your study.
- Prior to the exchange of any data for research purposes, additional protections, in the form of additional HIPAA agreements, are required to maintain the privacy and confidentiality of the participant's data. The type of agreement required depends on the nature of the data being disclosed and the financial contracts in place for the study. When an agreement (such as Confidentiality/Non-Disclosure Agreement, Data Use Agreement or Business Associate Agreement) is required, please promptly contact Tom Dang at (310) 816-6419.
- If your study discloses PHI for research purposes involving fewer than 50 participants and is allowed by an IRB waiver of authorization, and is not part of a limited data set under a data use agreement, the PI is required to submit a HIPAA disclosure tracking form to the KPMAS HIMS Department within 10 business days. For more information, please contact Nancy Doellgast at (301) 816-5860.
- If your study or IRB-approved study documents require ANY modification, you must seek IRB approval for these changes before they are implemented **except** when necessary to eliminate apparent immediate hazards to one or more subjects.
- You must promptly notify the IRB of any unanticipated adverse events affecting subjects or controls, as well as any complications that occur during any experimental procedure.
- MAPMG policies require that publications or presentations be reviewed by the Mid-Atlantic Permanente Research Institute prior to submission. For more information, contact Dr. Michael Horberg at (301) 816-6302.

Wishing you much success in all your research endeavors,



La Trina B. Neal  
Director, Human Research Protections/IRB Administrator

## **Kaiser Permanente of the Mid-Atlantic States IRB Important Information about Your IRB Approval**

If you have IRB-related questions, please call 301/816.6572 (8/297-6572) or e-mail the IRB Administrator ([latrina.b.neal@kp.org](mailto:latrina.b.neal@kp.org)).

**IRB approval does not necessarily constitute approval to begin your new study.** Conditional approval from the IRB subject to specified items means that the pending items must be submitted to and approved by the IRB before research activities can begin. In addition, other (non-IRB) approvals may be needed.

**Study Compliance:** IRB approval is contingent upon your continued compliance with all IRB conditions and requirements. **Noncompliance** can result in suspension or termination of your research project. As the PI, it is your responsibility to understand and comply with the requirements of the IRB and to assure that all co- and sub-investigators and research staff understand and comply with these requirements.

**Study-Related Documents:** The IRB must approve all study-related documents, including consent forms, survey instruments, recruitment flyers or letters, and telephone scripts before they can be used in a research study.

**Modifications:** If any IRB-approved study, or study-related document or procedure, requires revision during the course of the study, the IRB must approve the revision before implementation (see SOP KPMA-009). An IRB modification request should be submitted for this purpose. Modifications may be made prior to IRB approval **only** when necessary to protect the safety, rights, or welfare of research participants. These changes must be reported within ten days to the IRB.

**Protocol Violations (PV):** Departures from the IRB-approved research plan that could jeopardize the health, safety, welfare, and privacy of a research participant or the integrity of the study must be reported to the IRB as a **protocol violation** (see SOP KPMA-021).

**Informed Consent:** Unless specifically waived by the IRB and documented in writing, you must assure documentation of informed consent using a consent form approved by the KPMAS IRB. You will receive the approved consent form (via e-mail in an Acrobat PDF file) for you to copy and use. You also will receive the "Research Participants' Bill of Rights," which you must give to each prospective participant with the consent form.

You may **not** retype the consent form or change it in any way. If the consent form requires any revision, you must submit to the IRB a modification request along with a copy of the most recent IRB-approved consent form showing your proposed changes. You can request a Word version of the consent form by contacting the IRB office. Use Track Changes to indicate all changes in the Word file or write clearly in pen. You may not use a revised consent form until the IRB approves it and you receive the PDF file from the IRB office.

**Continuing Review:** Because all IRB-approved research requires review and reapproval at least once per year, you must submit progress reports. If your IRB approval expires by even one day, study-related activities must stop until the IRB reapproves the research. When your project is over (all data analysis activities are complete), you must submit a final report to the IRB. A copy of the consent form currently in use for the study must accompany all progress and final reports. **It is your responsibility to track the study expiration date** and submit a progress or final report in time for reapproval or study closure before the study expires.

**Adverse Events (AE):** You must promptly report to the IRB all unanticipated serious adverse events experienced by KP study participants. Specific reporting guidelines and forms are available from the IRB. Please review KPMAS adverse events reporting policies at the KPMAS Research web site for specific guidelines (see SOP KPMA-012). A copy of the consent form currently in use for the study must accompany your AE submission.