

Application for Round 3 QIBA Project Funding

<b>Title of Proposal:</b> A Pilot Study of the Effect of Steatosis and Inflammation on Shear Wave Speed for the Estimation of Liver Fibrosis Stage in Patients with Diffuse Liver Disease		
QIBA Committee/Subgroup: Ultrasound/ Clinical Subcommittee		
NIBIB Task Number(s) which this project addresses:		
Project Coordinator or Lead Investigator Information: <b>Anthony E. Samir</b>		
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Institution/Company: <b>Massachusetts General Hospital</b>		
Amount Requested:		

**Project Description**

It is well established that the liver fibrosis severity correlates with liver stiffness, which can be non-invasively estimated by quantifying shear wave speed (SWS) in the liver parenchyma. Numerous confounding factors may influence liver parenchymal shear wave speed; examples include meals, BMI and central venous pressure. Two factors known to be of central clinical import are liver steatosis and inflammation.

This project has two components: **(1)** a comprehensive review of the existing SWE and transient elastography (TE) literature to identify and rank – in order of perceived clinical importance – clinical factors that potentially influence the speed of shear waves within the liver parenchyma. **(2)** A pilot study focused on the effect of liver steatosis and inflammation on shear wave speed. Evaluation of these two factors, particularly steatosis, is also of value for possible inclusion of these critical conditions in future QIBA ultrasound profiles.

We aim to enroll 100 subjects **(Annexure I)** at our hospital. These subjects will undergo shear wave elastography at the time of liver biopsy. We will add this data to 130 subjects previously studied at our institution. Each liver biopsy will be blind read by a single sub-specialist pathologist in a format established by a multi-disciplinary specialist group **(Annexure II)**. Standardized shear wave elastography acquisitions will be obtained, including multiple measurements obtained at end expiration in the superficial right liver lobe. We anticipate 200-230 subjects will permit multivariate analysis of association between steatosis, inflammation and SWS.