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The Hepatitis B Research Network

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In parallel with the Consensus Development Conference on Management of Chronic Hepatitis B, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) held the initial organizational steering committee meeting of the **Hepatitis B Research Network**. The establishment of this Network was the centerpiece of a large initiative in hepatitis B that was directed at making progress in the understanding, prevention and control of this important liver disease. This initiative was the result and a part of the Trans-NIH Action Plan for Liver Disease Research (<http://liverplan.niddk.nih.gov>) that was published in December 2004 and laid out a series of specific research goals for liver disease research for the next ten years. The Action Plan represented the collective efforts of more than 250 individuals including liver research investigators, academicians, practicing physicians, researchers and representatives from industry, NIH staff and lay advocates who worked together to prioritize liver disease research goals. The research goals were directed at specific advances that would translate into substantial improvement in the understanding, prevention and treatment of liver diseases. Within this report, key research priorities for hepatitis B research were given in the chapter on viral hepatitis many of which still remain incompletely resolved. To help meet these goals, the NIH sponsored this 2008 Consensus Development Conference on Management of Hepatitis B, but also set into motion a prospective clinical research network of investigators charged with the mission to provide new insights into the pathogenesis of hepatitis B and help define the most appropriate therapy of this disease in its multiple clinical forms and in the different populations that it affects.

The creation of a Hepatitis B Research Network was announced in a Request for Applications published in October 11, 2007 using a cooperative agreement (U01) grant mechanism. Grant applications for clinical centers, research cores and a data coordinating center were received by February 27, 2008, reviewed on July 10-11, 2008 and awarded on September 30, 2008, in time for the initial, organizational meeting of the Network to be held at the time of the NIH Consensus Conference. Organizationally, the Network is composed of 13 Clinical Centers with expertise in the diagnosis, management, and treatment of chronic hepatitis B; one Data Coordinating Center to provide statistical, protocol, and logistical support for the network; and an Immunology Core to investigate immune factors that are important in hepatitis B. The Network will also be supported by a virology testing core and a

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specimen repository. The NIDDK has committed \$45 million over seven years towards this endeavor. The thirteen Clinical Center Principal Investigators (and some sites with multiple Co-Investigators) in alphabetical order are:

- Robert Carithers, Jr, Kris Kowdley, Brian McMahon (University of Washington, Seattle, WA; Virginia Mason Medical Center, Seattle, WA; & Alaska Native Medical Center, Anchorage, AL);
- Adrian M. Di Bisceglie (Saint Louis University, St Louis, MO);
- Michael Fried (University of North Carolina, Chapel Hill, NC);
- Marc G. Ghany, T. Jake Liang, David E. Kleiner (NIH Clinical Center, Bethesda, MD);
- Steven Han, Tram Tran, Tse-Ling Fong (University of California Los Angeles; Cedars-Sinai Medical Center; & University of Southern California, Los Angeles, CA);
- E. Jenny Heathcote, Jordan Feld, David Wong (University of Toronto, Toronto, Canada);
- W. Ray Kim (Mayo Clinic, Rochester, MN),
- Daryl T-Y Lau, Raymond T. Chung (Beth Israel Deaconess Hospital & Massachusetts General Hospital, Boston, MA);
- William Lee, Robert P. Perrillo (University of Texas Southwestern & Baylor Medical Center, Dallas, TX);
- Anna S.F. Lok (University of Michigan, Ann Arbor, MI);
- Mitchell Schiffman (Virginia Commonwealth University, Richmond, VA);
- Kathleen Schwarz (Johns Hopkins University, Baltimore, MD);
- Norah A. Terrault, Mandana Khalili, Natalie Bzowej (University of California San Francisco & California Pacific Medical Center, San Francisco, CA).

The Immunology Center Principal Investigator is:

- Kyong-Mi Chang (University of Pennsylvania, Philadelphia, PA)

The Data Coordinating Center (DCC) Principal Investigator is:

- Steven Belle (University of Pittsburgh, Pittsburgh, PA).

From the NIDDK, Dr. Patricia Robuck serves as the Project Officer and Dr. Edward Doo as the chief Scientific Officer. Drs. Jay H. Hoofnagle, Leonard B. Seeff, Elizabeth Wright and Jay Everhart of the Liver Diseases Research Branch, NIDDK, serve as scientific advisors. Additional participants include representatives from the Center for Disease Control and Prevention (CDC) and the National Institute of Allergy and Infectious Disease (NIAID). The Network is charged with developing a randomized controlled trial of long-term therapy of hepatitis B as well as a large-scale prospective cohort study to follow chronic hepatitis B patients longitudinally with the overarching goal of addressing the research priorities identified at this and prior research meetings towards the alleviation of this condition. Ancillary studies directed at elucidating the pathogenesis of the various stages and forms of hepatitis B and identifying biomarkers of disease activity and stage, as well as conduct of smaller, more innovative trials of therapy in special populations of patients with hepatitis B are also planned. The timing of the NIH Consensus Conference on Management of Hepatitis B was fortunate, allowing for the special focus on “Research Needs for the Future” from each speaker to provide important directions for the research agenda of the Hepatitis B

Research Network. Additional information about the Hepatitis B Research Network is available on its website: www.hepbnet.org

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Abbreviations

NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institutes of Health
CDC	Center for Disease Control and Prevention
NIAID	National Institute of Allergy and Infectious Diseases