# ONGOING CLINICAL PROTOCOLS AT OCHSNER

**West Nile Virus**

**Title: Protocol for study of West Nile fever in Southeastern Louisiana.**

**Sponsor:** Centers for Disease Control and Prevention

**Investigator:** Sandra Kemmerly, MD 504-842-4648; Mike Bunning, MD 970-266-3565

**Study Objectives:** To describe the clinical spectrum and course of illness of persons with febrile WNV disease, estimate the incidence and burden of human West Nile fever in areas of intense epizootic WNV activity and quantify WNV viremia in the acute phase of illness to help assess the role of human hosts in WNV transmission.

**Inclusion Criteria:** Laboratory-confirmed WNV infection

**Hepatitis B**

**Title: A randomized, open label, multicenter pilot study of Pegasys and Epivir-HBV as initial treatment of HBeAg-negative chronic hepatitis B infection.**

**Sponsor:** Ochsner Clinic Foundation

**Investigator:** Robert Perrillo, MD 504-842-4015

**Study Objective:** To assess Pegasys™ and Pegasys™ in combination with Epivir-HBV™ based on sustained virological response in patients with chronic hepatits B who do not express HBeAg.

**Inclusion Criteria:**

- > 18 years of age with elevated ALT
- Virologically confirmed HBeAg-negative hepatitis B

**Exclusion Criteria:**

- Previous treatment with interferon or Epivir-HBV™
- Other liver disease, anemia, HIV, hepatocellular carcinoma, pre-existing severe depression or psychiatric disease, cardiac disease, renal disease, seizure disorders or severe retinopathy

**Title: Randomized trial of lamivudine and intramuscular hepatits B immune globulin vs. lamivudine montherapy as maintenance prophylaxis against recurrent hepatitis B post-liver transplantation in high-risk patients.**

**Sponsor:** National Institutes of Health

**Investigator:** Robert Perrillo, MD 504-842-4015

**Study Objective:** To compare the safety, efficacy and cost-effectiveness of lamivudine and IM HBIG vs. lamivudine monotherapy in the prevention of recurrent hepatitis B after the first year post-transplant in high-risk patients.

**Inclusion Criteria:**

- > 13 years of age > 1 year post-liver or combined liver-kidney transplantation for HBV-induced liver/disease
- High or unknown risk of recurrent hepatitis B post-transplant
- Received combination prophylaxis of HBIG and lamivudine throughout first year post-transplant
- Phenotypic evidence of lamivudine resistance pre-transplant, concomitantly receiving adefovir dipovoxil through first year post-transplant

**Exclusion Criteria:**

- Required transplantation of organs other than liver or liver/kidney
- Evidence of recurrent hepatitis B first year post-transplant
- Other liver disease: chronic hepatitis C, alcoholic liver disease, autoimmune hepatitis or metabolic liver disease
- Received lamivudine monotherapy during first year post-transplant
- Phenotypic resistance to lamivudine pre-transplant and cannot tolerate adefovir dipivoxil first year post-transplant
- Receiving prednisone for prevention of rejection
- Recurrent hepatocellular carcinoma during first year post-transplant

**Hepatitis C**

**Title: Use of peginterferon alfa-2b and ribavirin for the treatment of patients with chronic hepatitis C with normal ALT levels.**

**Sponsor:** St. Louis University Health Sciences Center

**Investigator:** Robert Perrillo, MD 504-842-4015

**Study Objective:** To compare virologic response rate of chronic hepatitis C patients with normal ALT levels vs. historical response rates of patients with elevated ALT levels with the use of peginterferon alfa-2b and ribivirin at standard dosages.

**Inclusion Criteria:**

- Patients > 18 years of age with liver biopsy results (within previous 36 months) consistent with chronic hepatitis C
- Compensated liver disease
- 3 ALT levels within normal range at least 1 month apart

**Exclusion Criteria**

- Abnormal alpha fetoprotein value within prior year
- Pregnancy or breastfeeding
- Prior treatment with interferon or other antiviral or immunomodulatory drug
- Advanced liver disease or chronic liver disease due to cause other than hepatitis C
- Evidence of existing cardiac disease
- Clinically significant retinal abnormalities

**Hospital Infections**

**Title: A multicenter, double blind, randomized, comparison study of the efficacy and safety of tigecycline to imipenem/cilastatin to treat complicated intra-abdominal infections in hospitalized subjects.**

**Sponsor:** Wyeth Pharmaceuticals

**Investigator:** Julia B. Garcia-Diaz, MD 504-842-4005

**Study Objective:** To compare the efficacy and safety of tigecycline to imipenem/cilastatin to treat complicated intra-abdominal infections in hospitalized subjects.

**Inclusion Criteria:**

- Hospitalized patients >18 years of age with complicated intra-abdominal infections
- Scheduled for or have had laparotomy, laparoscopy or percutaneous drainage of intra-abdominal abcess
- Received no more than 1 dose of an antibiotic after baseline abdominal culture

**Exclusion Criteria:**

- Anticipated antibiotic length < 5 days
- Concomitant treatment with gangiclovir
- Known or suspected hypersensitivity to tigecycline, tetracycline agents, imipenem, cilastitin or related compounds
- Existing liver disease or neutropenia
- Intra-abdominal infection known to be caused by one or more bacterial pathogens that are not susceptible to both test agents