**EXECUTIVE SUMMARY**

**Alcoholic Hepatitis Network Observational Study**

**Study Type**

Prospective, observational study

**Investigational Sites**

Indiana University; University of Louisville affiliated hospitals in Kentucky; University of Massachusetts Medical Center in Massachusetts; Mayo Clinic in Rochester, Minnesota; Cleveland Clinic Foundation, Ohio; University of Pittsburgh Medical Center in Pennsylvania; University of Texas at Southwestern in Dallas, Texas; and Virginia Commonwealth University in Richmond, Virginia

**Planned Number of Patients**

Approximately 1260 (720 subjects with alcoholic hepatitis (AH), 360 heavy drinkers without AH, and 180 healthy donors) will be enrolled.

**Objectives**

**PRIMARY OBJECTIVE:**  To collect and store clinical data to facilitate investigations of the epidemiology, diagnosis, pathophysiology, natural history, and treatment of alcoholic hepatitis.

**SECONDARY OBJECTIVE**: To develop a bio-specimen bank comprised of plasma, DNA, and other biological specimens obtained from patients with alcoholic hepatitis, heavy drinkers without clinical liver disease, and healthy subjects to support translational research in the pathophysiology of alcoholic hepatitis

**Methodology**

**Screening phase**: Subjects will be assessed for the eligibility criteria and a written informed consent will be obtained from the eligible subjects.

**Study phase:** Subjects will undergo history taking, physical examination, questionnaire administration, and laboratory tests. Biosamples including serum/plasma, peripheral mononuclear cells (at select sites), genomic DNA, stool samples (when available), urine, and liver tissue (where available) will be obtained.

**Follow up phase:** Alcoholic hepatitis subjects will be followed for 360 days, Heavy drinking controls for 180 days, and healthy controls subjects for 1 day (at initial meeting for baseline).