

IVRN Specimen Collections

HIV

The CD8 rescue collection: Stored peripheral blood mononuclear cells (PBMC) and plasma collected at multiple timepoints over a span of 5 years (1992 –1996) are available from HIV-infected individuals. Subjects have at least one leucapheresis bag of cryopreserved PBMC (~6x10⁹ cells/bag) collected at the first time point, all subjects have multiple longitudinally collected vials of plasma as well as separated CD4+, and CD8+ cells (~5-10x10⁶ cells/vial separated by Dynabeads). The subjects span the spectrum of HIV management from being anti-retroviral naïve and clinically stable through to rapid progressors who have received multiple HAART regimens over the time period. For each subject at each sampling point, the clinical status and T cell counts are available.

The STEAL study: This NCHECR coordinated clinical trial is evaluating the safety and efficacy of simplified dual-NRTI-based antiretroviral therapy with either once-daily ABC-3TC fixed dose combination or once-daily TDF-FTC fixed dose combination in HIV-infected adults currently receiving two NRTIs as part of suppressive antiretroviral therapy. Serum, plasma and PBMC samples for IVRN studies are being collected from 50 subjects (25 from each arm) at baseline, 3 months and then 6 monthly intervals for 24 months. For each subject at each sampling point, the clinical status, T cell counts and viral load data are available.

HCV

The ATAHC study: This is a prospective, non-randomised, dual arm longitudinal cohort study of individuals with newly acquired HCV infection who either opt to undergo treatment for 24 weeks with pegylated interferon- α or remain untreated. Plasma and PBMC samples for IVRN studies are available from approximately 30 subjects in the treatment arm at baseline, 4, 8, 12 and 24 weeks and then at 12 and 24 months. For each subject at each sampling point, the ALT and viral load data are available.

The Prince of Wales HCV collection: Longitudinally collected PBMC and serum samples are available from a matched cohort of patients with genotype 1 or 3 HCV infection who received combination therapy with interferon- α and ribavirin and achieved a sustained virological response (n=10) or were non-responders (n=9). The sample sets include baseline and 3-6 monthly intervals thereafter. For each subject the histopathological data from the pre-treatment liver biopsy and the on-treatment ALT is available.

Co-infection

HIV/HBV: Samples are being stored from an NIH-funded longitudinal cohort study of HIV/HBV co-infection in individuals receiving HBV-active HAART. PBMC samples are available from approximately 70 subjects at 0, 6, 12, and 18 month timepoints. For each subject at each sampling point, the ALT and HBV DNA loads are available, as well as the T cell counts and HIV viral load data.

HIV/HCV: Samples are being stored from subjects with HIV/HCV co-infection with three comparison groups: (i) co-infected patients commencing HAART, either de novo or after a period of six months or more without treatment, (ii) co-infected patients on stable HAART therapy, (iii) co-infected patients not receiving treatment. Serum, plasma, and PBMC samples are being collected at study timepoints are week 0 (before commencement of HAART), week 2, 4, 8, 12, 24. For each subject at each sampling point, the ALT and HCV viral loads are available, as well as the T cell counts and HIV viral load data

Data

Clinical and laboratory data on individual specimens within each of these collections is stored in the Blood and Tissue Samples Inventory System (BATSIS) database. Read-only access to BATSIS to view specimen details can be arranged upon request to the IVRN Project Coordinator.