



**DRUG DOSE AND METHOD OF ADMINISTRATION:** antiretroviral therapy at any stage in consultation with their treating clinicians in accordance with current standard of care guidelines.

**MAIN PARAMETERS OF EFFICACY:** N/A

**DATA ANALYSES:** Analysis of factors associated with disease progression will be undertaken on an annual basis including, CD4 decline to <350 cells/mm, plasma levels of HIV-1 RNA, serial CD4/CD8 counts, meeting the criteria for initiation of ARV therapy, progression to AIDS or death.

**ACTIVE SITES:** **Sydney:** St Vincent's Hospital, AIDS Research Initiative, East Sydney Doctors, Holdsworth House Medical Practice, Taylor Square Private Clinic and Albion St Clinic

**PROTOCOL:** Protocol version 1.2, May 2009

**SPONSOR(S):** Funding through NMHRC grant

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## Protocol Synopsis

Title	<b>PHIIDO</b> (Primary HIV Infection Identification Data Observational)
Protocol number	PHIIDO; Draft version 1.2
Objectives	<ol style="list-style-type: none"> <li>1. Recruit and follow up a cohort of people with documented evidence of primary (acute and early) HIV infection not on antiretroviral therapy</li> <li>2. Provide the clinical and laboratory framework to characterise immunological responses/viral events that occur early in the course of HIV infection in untreated subjects with a focus on factors that determine natural viral control.</li> </ol>
Study design	Prospective observational cohort study
Patient population	Subjects identified with acute/ early HIV infection not on Antiretroviral therapy
Treatment options and duration	Initial enrolment focussed on patients who will not receive treatment for PHI; decision to commence treatment after enrolment is at the clinician (and patient's) discretion. If patients commence therapy they will be offered the Phaedra Extension protocol.
Measures of disease progression	<p>CD4 decline to <math>&lt;350</math> cells/mm<sup>3</sup></p> <p>Plasma levels of HIV-1 RNA</p> <p>Meeting the criteria for initiation of ARV therapy</p> <p>Progression to AIDS or death</p>
Data analysis	This group to be used to study natural history of disease, so no sample size calculated

## Study Flow Chart

	Screening	Baseline	Wk4	Wk12	Wk24	Wk52	WK 78	Wk 104**
PHI symptoms	√	√	√					
Eligibility	√	√						
Demographics		√						
Consent		√						
Antiretroviral usage *		√	√	√	√	√	√	√
HIV related disease		√	√	√	√	√	√	√
Western blot/ELISA	√	√ (If not done at screening)						
T-cell subsets		√	√	√	√	√	√	√
Viral load		√	√	√	√	√	√	√
Plasma storage <sup>γ</sup>		√	√	√	√	√	√	√
Serum storage		√	√	√	√	√	√	√
Cell storage		√	√	√	√	√	√	√